him will ever forget him. He is sadly missed and that smile of his will never be forgotten.'' Schuyler's mom Colleen also talked about his incredibly warm smile that will be forever in her mind.

A fellow soldier wrote, ''I was proud to have served with [Patch] in Afghanistan in 2006–2007. He was a good guy and liked to make the best of the situation.''

A friend wrote, ''We will all miss him and we all love him very much. He was the kind of guy who could cheer you up on your worst day and the most outgoing person I'll ever know. Thank you Schuyler for all the great memories we had and thank you so much for serving to protect all of us. I love you.''

Captain Jon Prain, a National Guard chaplain who spoke at his funeral, summed up Schuyler's life well when he said, ''He heard freedom's call. He paid freedom's price, so that we all might enjoy the benefits of freedom . . . He was, and always shall be, an American soldier.''

Schuyler lived a life of love for his family, friends, and country. He will be remembered by many for his contagious smile and warm, affectionate personality. I am honored to pay tribute to this true American hero who volunteered to go into the fight and gave the ultimate sacrifice by giving up his life for our freedom.

AMENDMENTS SUBMITTED AND PROPOSED

SA 1230. Mr. JOHANNS (for himself, Mr. INHOFE, Mr. CHAMBLISS, Mr. ISAKSON, Mr. RISCH, Mr. VITTER, Mr. BARRASSO, Mr. MCCAIN, Mr. COBURN , Mr. MCCONNELL, Mr. BOND, Mr. ROBERTS, Mr. HATCH, Mr. MARTINEZ, Mrs. HUTCHISON, Mr. WICKER, Mr. BUNNING, Mr. KYL, Mr. SESSIONS, Mr. DEMINT, Mr. CORNYN, Mr. THUNE, and Mr. VOINOVICH) submitted an amendment intended to be proposed by him to the bill H.R. 1256, to protect the public health by providing the Food and Drug Administration with certain authority to regulate tobacco products, to amend title 5, United States Code, to make certain modifications in the Thrift Savings Plan, the Civil Service Retirement System, and the Federal Employees' Retirement System, and for other purposes; which was ordered to lie on the table.

SA 1231. Mr. ENZI submitted an amendment intended to be proposed by him to the bill H.R. 1256, supra; which was ordered to lie on the table.

SA 1232. Mr. ENZI submitted an amendment intended to be proposed by him to the bill H.R. 1256, supra; which was ordered to lie on the table.

SA 1233. Mr. MCCAIN submitted an amendment intended to be proposed by him to the bill H.R. 1256, supra; which was ordered to lie on the table.

SA 1234. Mr. DEMINT submitted an amendment intended to be proposed by him to the bill H.R. 1256, supra; which was ordered to lie on the table.

SA 1235. Mr. LAUTENBERG submitted an amendment intended to be proposed by him to the bill H.R. 1256, supra; which was ordered to lie on the table.

SA 1236. Mr. BUNNING submitted an amendment intended to be proposed by him to the bill H.R. 1256, supra; which was ordered to lie on the table.

SA 1237. Mr. BUNNING submitted an amendment intended to be proposed by him to the bill H.R. 1256, supra; which was ordered to lie on the table.

SA 1238. Mr. BUNNING submitted an amendment intended to be proposed by him to the bill H.R. 1256, supra; which was ordered to lie on the table.

SA 1239. Mr. BUNNING submitted an amendment intended to be proposed by him to the bill H.R. 1256, supra; which was ordered to lie on the table.

SA 1240. Mr. ENZI submitted an amendment intended to be proposed by him to the bill H.R. 1256, supra; which was ordered to lie on the table.

SA 1241. Mr. BROWNBACK (for himself, Mr. KYL, and Mr. BOND) submitted an amendment intended to be proposed by him to the bill H.R. 1256, supra; which was ordered to lie on the table.

SA 1242. Mr. BAYH (for himself, Ms. MURKOWSKI, Mr. BURRIS, Mr. LIEBERMAN, Mr. WARNER, Mr. WEBB, and Mr. NELSON of Nebraska) submitted an amendment intended to be proposed by him to the bill H.R. 1256, supra; which was ordered to lie on the table.

SA 1243. Mr. DEMINT (for himself, Mr. KYL, Mr. BUNNING, Mr. MARTINEZ, Mr. JOHANNS, Mr. RISCH, Mr. CRAPO, Mr. MCCONNELL, Mr. BOND, Mr. CORNYN, Mr. CHAMBLISS, Mr. COBURN, Mr. ROBERTS, Mr. INHOFE, Mr. BENNETT, Mr. BURR, and Mr. BROWNBACK) submitted an amendment intended to be proposed by him to the bill H.R. 1256, supra; which was ordered to lie on the table.

SA 1244. Mr. BURR (for himself and Mrs. HAGAN) submitted an amendment intended to be proposed by him to the bill H.R. 1256, supra; which was ordered to lie on the table.

SA 1245. Ms. STABENOW (for herself and Ms. MURKOWSKI) submitted an amendment intended to be proposed by her to the bill H.R. 1256, supra; which was ordered to lie on the table.

SA 1246. Mr. BURR (for himself and Mrs. HAGAN) submitted an amendment intended to be proposed to amendment SA 1247 proposed by Mr. DODD to the bill H.R. 1256, supra.

SA 1247. Mr. DODD proposed an amendment to the bill H.R. 1256, supra.

SA 1248. Mrs. FEINSTEIN (for herself, Mr. BROWNBACK, and Ms. STABENOW) submitted an amendment intended to be proposed by her to the bill H.R. 1256, supra; which was ordered to lie on the table .

SA 1249. Mrs. HAGAN submitted an amendment intended to be proposed by her to the bill H.R. 1256, supra; which was ordered to lie on the table.

SA 1250. Mrs. HAGAN submitted an amendment intended to be proposed by her to the bill H.R. 1256, supra; which was ordered to lie on the table.

SA 1251. Mrs. HAGAN submitted an amendment intended to be proposed by her to the bill H.R. 1256, supra; which was ordered to lie on the table.

SA 1252. Mrs. HAGAN submitted an amendment intended to be proposed by her to the bill H.R. 1256, supra; which was ordered to lie on the table.

SA 1253. Mrs. HAGAN submitted an amendment intended to be proposed by her to the bill H.R. 1256, supra; which was ordered to lie on the table.

SA 1254. Mrs. HAGAN submitted an amendment intended to be proposed by her to the bill H.R. 1256, supra; which was ordered to lie on the table.

SA 1255. Ms. STABENOW (for herself, Mr. BROWNBACK, Ms. MIKULSKI, Mr. VOINOVICH, Mrs. SHAHEEN, Mr. BOND, Mr. BURRIS, Mr. DURBIN, Mr. LEVIN, and Mr. BROWN) submitted an amendment intended to be proposed by her to the bill H.R. 1256, supra; which was ordered to lie on the table.

SA 1256. Mr. SCHUMER (for Mr. LIEBERMAN (for himself, Ms. COLLINS, Mr. AKAKA, and Mr. VOINOVICH)) proposed an amendment to amendment SA 1247 proposed by Mr. DODD to the bill H.R. 1256, supra.

TEXT OF AMENDMENTS

SA 1230. Mr. JOHANNS (for himself, Mr. INHOFE, Mr. CHAMBLISS, Mr. ISAKSON, Mr. RISCH, Mr. VITTER Mr. BARRASSO, Mr. MCCAIN, Mr. COBURN, Mr. MCCONNELL, Mr. BOND, Mr. ROBERTS, Mr. HATCH, Mr. MARTINEZ, Mrs. HUTCHISON, Mr. WICKER, Mr. BUNNING, Mr. KYL, Mr. SESSIONS, Mr. DEMINT, Mr. CORNYN, Mr. THUNE, and Mr. VOINOVICH) submitted an amendment intended to be proposed by him to the bill H.R. 1256, to protect the public health by providing the Food and Drug Administration with certain authority to regulate tobacco products, to amend title 5, United States Code, to make certain modifications in the Thrift Savings Plan, the Civil Service Retirement System, and the Federal Employees' Retirement System, and for other purposes; which was ordered to lie on the table; as follows:

At the appropriate place, insert the following:

SEC. ___. CONGRESSIONAL APPROVAL OF CERTAIN TARP EXPENDITURES.

Notwithstanding any other provision of law, including any provision of the Emergency Economic Stabilization Act of 2008, on and after May 29, 2009, no funds may be disbursed or otherwise obligated under that Act to any entity, if such disbursement would result in the Federal Government acquiring any ownership of the common or preferred stock of the entity receiving such funds, unless the Congress first approves of such disbursement or obligation.

SA 1231. Mr. ENZI submitted an amendment intended to be proposed by him to the bill H.R. 1256, to protect the public health by providing the Food and Drug Administration with certain authority to regulate tobacco products, to amend title 5, United States Code, to make certain modifications in the Thrift Savings Plan, the Civil Service Retirement System, and the Federal Employees' Retirement System, and for other purposes; which was ordered to lie on the table; as follows:

Strike section 2.

SA 1232. Mr. ENZI submitted an amendment intended to be proposed by him to the bill H.R. 1256, to protect the public health by providing the Food and Drug Administration with certain authority to regulate tobacco products, to amend title 5, United States Code, to make certain modifications in the Thrift Savings Plan, the Civil Service Retirement System, and the Federal Employees' Retirement System, and for other purposes; which was ordered to lie on the table; as follows:

In section 919 of the Federal Food Drug, and Cosmetic Act (as added by section 101), add at the end the following:

''(d) ADJUSTMENTS.—

''(1) INFLATION ADJUSTMENT.—With respect to fiscal years beginning with fiscal year

2020, the amount provided for in subsection (b)(1)(K) for a fiscal year shall be adjusted by the Secretary by notice, published in the Federal Register, by the greater of—

''(A) the total percentage change that occurred in the Consumer Price Index for all urban consumers (all items, United States city average), for the 12 month period ending June 30 preceding the fiscal year for which the amount is being adjusted;

''(B) the total percentage change for the previous fiscal year in basic pay under the General Schedule in accordance with section 5332 of title 5, United States Code, as adjusted by any locality-based comparability payment pursuant to section 5304 of such title for Federal employees stationed in the District of Columbia; or

''(C) the average annual change in the cost, per full-time equivalent position of the Food and Drug Administration, of all personnel compensation and benefits paid with respect to such positions, for the first 5 years of the most recent 6-year period ending on September 30 of the year for which such amount is being adjusted.

The adjustment made with respect to each fiscal year under this subsection shall be added on a compounded basis to the sum of all adjustments made for each such fiscal year after fiscal year 2020.

''(2) WORKLOAD ADJUSTMENT.—Beginning with fiscal year 2020, after the amount provided for in subsection (b)(1)(K) is adjusted for a fiscal year in accordance with paragraph (1), the fee revenues shall be further adjusted for such fiscal year to account for changes in the workload of the Secretary in carrying out the responsibilities provided for under this chapter. With respect to such adjustment, the following shall apply:

''(A) The adjustment shall be determined by the Secretary based on a weighted average of the change in the total number of applications under sections 910 and 911 during the previous 12-month period. The Secretary shall publish in the Federal Register the fee revenues and fees resulting from the adjustment and the supporting methodologies.

''(B) Under no circumstances shall the adjustment result in fee revenues for a fiscal year that are less than the fee revenues for fiscal year 2019 (as established under subsection (b)(1)(K)), as adjusted under paragraph (1).''.

SA 1233. Mr. MCCAIN submitted an amendment intended to be proposed by him to the bill H.R. 1256, to protect the public health by providing the Food and Drug Administration with certain authority to regulate tobacco products, to amend title 5, United States Code, to make certain modifications in the Thrift Savings Plan, the Civil Service Retirement System, and the Federal Employees' Retirement System, and for other purposes; which was ordered to lie on the table; as follows:

On page 199, line 10, insert '', except the term shall not include a member of the uniformed services'' before the period.

On page 199, strike lines 15 through 24.

On page 209, line 12, strike all through page 210, line 12.

SA 1234. Mr. DEMINT submitted an amendment intended to be proposed by him to the bill H.R. 1256, to protect the public health by providing the Food and Drug Administration with certain authority to regulate tobacco products, to amend title 5, United States Code, to make certain modifications in the Thrift Savings Plan, the Civil Service Retirement System, and the Federal Employees' Retirement System, and for other purposes; which was ordered to lie on the table; as follows:

At the appropriate place, insert the following:

SEC. ___. POINT OF ORDER TO KEEP HEALTH PLAN AND CHOICE OF DOCTOR AND TO LIMIT GOVERNMENT MANAGED, RATIONED HEALTH CARE.

(a) IN GENERAL.—In the Senate, it shall not be in order, to consider any bill, joint resolution, amendment, motion, or conference report that—

(1) eliminates the ability of Americans to keep their health plan or their choice of doctor (as determined by the Congressional Budget Office); or

(2) decreases the number of Americans enrolled in private health insurance plans, while increasing the number of Americans enrolled in government-managed, rationed health care (as determined by the Congressional Budget Office).

(b) WAIVER.—This section may be waived or suspended only by an affirmative vote of three-fifths of the Members of the Senate, dully chosen and sworn.

(c) APPEALS.—An affirmative vote of three-fifths of the Members of the Senate, duly chosen and sworn, shall be required to sustain an appeal of the ruling of the Chair on a point of order raised under this section.

SA 1235. Mr. LAUTENBERG submitted an amendment intended to be proposed by him to the bill H.R. 1256, to protect the public health by providing the Food and Drug Administration with certain authority to regulate tobacco products, to amend title 5, United States Code, to make certain modifications in the Thrift Savings Plan, the Civil Service Retirement System, and the Federal Employees' Retirement System, and for other purposes; which was ordered to lie on the table; as follows:

At the end of section 907(a)(1) of the Federal Food, Drug, and Cosmetic Act (as added by section 101(b)), add the following:

''(C) CHARACTERIZING FLAVOR.—For purposes of subparagraph (A), the term 'characterizing flavor' means—

''(i) a distinguishable flavor, taste, or aroma imparted by the tobacco product, or any smoke emanating from that product, prior to or during consumption that predominates over the flavor, taste, or aroma of the tobacco; or

''(ii) a distinguishable flavor, taste, or aroma other than tobacco used to advertise or market the tobacco product.

SA 1236. Mr. BUNNING submitted an amendment intended to be proposed by him to the bill H.R. 1256, to protect the public health by providing the Food and Drug Administration with certain authority to regulate tobacco products, to amend title 5, United States Code, to make certain modifications in the Thrift Savings Plan, the Civil Service Retirement System, and the Federal Employees' Retirement System, and for other purposes; which was ordered to lie on the table; as follows:

In section 4, strike subsection (b) and insert the following:

(b) AGRICULTURAL ACTIVITIES.—The provisions of this Act (or an amendment made by this Act) which authorize the Secretary to take action with regards to tobacco products shall not be construed to affect any authority of the Secretary of Agriculture regarding the growing, cultivation, curing or processing of raw tobacco. Nothing in this Act (or amendments) shall be construed to provide the Food and Drug Administration with any authority regarding the growing, cultivation, curing or processing of raw tobacco.

SA 1237. Mr. BUNNING submitted an amendment intended to be proposed by him to the bill H.R. 1256, to protect the public health by providing the Food and Drug Administration with certain authority to regulate tobacco products, to amend title 5, United States Code, to make certain modifications in the Thrift Savings Plan, the Civil Service Retirement System, and the Federal Employees' Retirement System, and for other purposes; which was ordered to lie on the table; as follows:

In section 919 of the Federal Food, Drug, and Cosmetic Act (as added by section 101) add the following:

''(f) TOBACCO GROWER GRANT PROGRAM.—

''(1) IN GENERAL.—The Secretary shall use a portion of the amounts collected under this section to award grants to producers of tobacco leaf, including tobacco growers, tobacco warehouses, and tobacco grower cooperatives, to enable such producers to offset the costs imposed under this chapter.

''(2) APPLICATION.—To be eligible for a grant under paragraph (1), a producer of tobacco leaf shall submit to the Secretary an application at such time, in such manner, and containing such information as the Secretary may require.

''(3) USE OF FUNDS.—A producer of tobacco leaf shall use amounts received under this subsection to pay the additional expenses associated with compliance by such producer with the requirements of this chapter.

''(4) AUTHORIZATION OF APPROPRIATIONS.—There is authorized to be appropriated, such sums as may be necessary to carry out this subsection.''.

SA 1238. Mr. BUNNING submitted an amendment intended to be proposed by him to the bill H.R. 1256, to protect the public health by providing the Food and Drug Administration with certain authority to regulate tobacco products, to amend title 5, United States Code, to make certain modifications in the Thrift Savings Plan, the Civil Service Retirement System, and the Federal Employees' Retirement System, and for other purposes; which was ordered to lie on the table; as follows:

In section 917 of the Federal Food, Drug, and Cosmetic Act (as added by section 101) strike subsections (a) and (b)(1) and insert the following:

''(a) ESTABLISHMENT.—Not later than 6 months after the date of enactment of the Family Smoking Prevention and Tobacco Control Act, the Secretary shall establish a 14-member advisory committee, to be known as the Tobacco Products Scientific Advisory Committee (in this section referred to as the 'Advisory Committee').

''(b) MEMBERSHIP.—

''(1) IN GENERAL.—

''(A) MEMBERS.—The Secretary shall appoint as members of the Tobacco Products Scientific Advisory Committee individuals who are technically qualified by training and experience in medicine, medical ethics, science, or technology involving the manufacture, evaluation, or use of tobacco products, who are of appropriately diversified

professional backgrounds. The committee shall be composed of—

''(i) 7 individuals who are physicians, dentists, scientists, or health care professionals practicing in the area of oncology, pulmonology, cardiology, toxicology, pharmacology, addiction, or any other relevant specialty;

''(ii) 1 individual who is an officer or employee of a State or local government or of the Federal Government;

''(iii) 1 individual as a representative of the general public;

''(iv) 1 individual as a representative of the interests of the tobacco manufacturing industry;

''(v) 1 individual as a representative of the interests of the small business tobacco manufacturing industry, which position may be filled on a rotating, sequential basis by representatives of different small business tobacco manufacturers based on areas of expertise relevant to the topics being considered by the Advisory Committee; and

''(vi) 3 individuals as representatives of the interests of the tobacco growers, with 1 such individual representing flu tobacco, one such individual representing burley tobacco, and one such individual representing dark tobacco.

''(B) CONFLICTS OF INTEREST.—No members of the committee, other than members appointed pursuant to clauses (iv), (v), and (vi) of subparagraph (A) shall, during the member's tenure on the committee or for the 18-month period prior to becoming such a member, receive any salary, grants, or other payments or support from any business that manufactures, distributes, markets, or sells cigarettes or other tobacco products.''.

SA 1239. Mr. BUNNING submitted an amendment intended to be proposed by him to the bill H.R. 1256, to protect the public health by providing the Food and Drug Administration with certain authority to regulate tobacco products, to amend title 5, United States Code, to make certain modifications in the Thrift Savings Plan, the Civil Service Retirement System, and the Federal Employees' Retirement System, and for other purposes; which was ordered to lie on the table; as follows:

At the appropriate place, insert the following:

SEC. ___. FARMER FEASIBILITY STUDY.

The Secretary of Health and Human Services, acting through the Food and Drug Administration shall conduct a study of the technical, logistical, and economic viability of any standards imposed under the Act (and the amendments made by this Act) on farmers regarding the growing, cultivation, curing, or processing of raw tobacco. Not later than 1 year after the date of enactment of this Act, the Secretary shall submit a report concerning the results of such study to the Committee on Agriculture of the Senate and the Committee on Agriculture of the House of Representatives.

SA 1240. Mr. ENZI submitted an amendment intended to be proposed by him to the bill H.R. 1256, to protect the public health by providing the Food and Drug Administration with certain authority to regulate tobacco products, to amend title 5, United States Code, to make certain modifications in the Thrift Savings Plan, the civil Service Retirement System, and the Federal Employees' Retirement System, and for other purposes; which was ordered to lie on the table; as follows:

At the appropriate place, insert the following:

TITLE ___—TOBACCO BUYOUT

SEC. ___01. ESTABLISHMENT OF TOBACCO BUYOUT PROGRAM.

Chapter IX of the Federal Food, Drug, and Cosmetic Act (as added by section 101 and amended by section 301) is further amended by adding at the end the following:

''SEC. 921. ESTABLISHMENT OF TOBACCO BUYOUT PROGRAM.

''(a) IN GENERAL.—The Secretary shall establish a program to require annual reductions in the sale of cigarettes.

''(b) REQUIREMENT.—

''(1) IN GENERAL.—Under the program under subsection (a), each tobacco product manufacturer shall annually certify to the Secretary that—

''(A) with respect to cigarettes made by such manufacturer, the total number of such cigarettes sold during the year for which the certification is submitted is 1 percent less than the total number of such cigarettes sold during the preceding year; or

''(B) such manufacturer has purchased an additional cigarette sales allotment from another manufacturer as provided for in subsection (c).

''(2) INITIAL CERTIFICATION.—With respect to the first year for which a certification is submitted by a tobacco product manufacturer, the 1 percent reduction required under paragraph (1)(A) with respect to the sale of cigarettes shall be determined using the amount of such manufacturer's cigarettes sold in the highest sales year during the preceding 5-year period (as determined by the Secretary).

''(c) ADDITIONAL CIGARETTE SALES ALLOTMENT.—

''(1) IN GENERAL.—A tobacco product manufacturer (referred to in this subsection as the 'contracting manufacturer') to which this section applies may enter into a contract with one or more additional manufacturers (referred to in this subsection as a 'decreased sales manufacturer') to purchase from such manufacturers an additional sales allotment.

''(2) REQUIREMENT.—A contract entered into under paragraph (1) shall—

''(A) require the decreased sales manufacturer to provide for a further reduction in the total number of cigarettes sold during the year involved (beyond that required under subsection (b)(1)) by an amount equal to the additional sales allotment provided for in the contract; and

''(B) permit the contracting manufacturer to increase the total number of cigarettes sold during the year involved by an amount equal to the additional sales allotment provided for in the contract.

''(3) ADDITIONAL SALES ALLOTMENT.—In this subsection, the term 'additional sales allotment' means the number of cigarettes by which the decreased sales manufacturer agrees to further reduce its sales during the year involved.

''(d) ENFORCEMENT.—

''(1) IN GENERAL.—A tobacco product manufacturer that fails to comply with the requirement of subsection (b) for any year shall be subject to a penalty in an amount equal to $2 multiplied by the number of cigarettes by which such manufacturer has failed to comply with such subsection (b). Amounts collected under this paragraph shall be used to carry out paragraph (2).

''(2) TOBACCO USE COUNTER-ADVERTISING.—The Secretary, acting through the Administrator of the Substance Abuse and Mental Health Services Administration, shall carry out a campaign of counter-advertising with respect to tobacco use. The campaign shall consist of the placement of pro-health advertisements regarding tobacco use on television, on radio, in print, on billboards, on movie trailers, on the Internet, and in other media.

''(e) PROCEDURES.—The Secretary shall develop procedures for—

''(1) the submission and verification of certificates under subsection (a);

''(2) the administration and verification of additional cigarette sales allotment contracts under subsection (c); and

''(3) the imposition of penalties under subsection (d).''.

SA 1241. Mr. BROWNBACK (for himself, Mr. KYL, and Mr. BOND) submitted an amendment intended to be proposed by him to the bill H.R. 1256, to protect the public health by providing the Food and Drug Administration with certain authority to regulate tobacco products, to amend title 5, United States Code, to make certain modifications in the Thrift Savings Plan, the Civil Service Retirement System, and the Federal Employees' Retirement System, and for other purposes; which was ordered to lie on the table; as follows:

At the end of the bill, add the following:

DIVISION C—DESIGNATION OF NORTH KOREA AS STATE SPONSOR OF TERRORISM

SEC. 101. FINDINGS.

Congress makes the following findings:

(1) On October 11, 2008, the Department of State removed North Korea from its list of state sponsors of terrorism, on which it had been placed in 1988.

(2) North Korea was removed from that list despite its refusal to account fully for its abduction of foreign citizens, proliferation of nuclear and other dangerous technologies and weapon systems to other state sponsors of terrorism, or its commission of other past acts of terrorism.

(3) On March 17, 2009, American journalists Euna Lee and Laura Ling were abducted near the Chinese-North Korean border by agents of the North Korean government.

(4) The Government of North Korea has announced that these United States citizens will stand trial on June 4, 2009, where they face imprisonment in a North Korean prison camp.

(5) On April 5, 2009, the Government of North Korea tested a long-range ballistic missile in violation of United Nations Security Council Resolutions 1695 and 1718.

(6) After purportedly disabling its Yongbyon nuclear facility in 2008, the Government of North Korea has since announced its re-commissioning.

(7) On April 15, 2009, the Government of North Korea announced it was expelling international inspectors from its Yongbyon nuclear facility and ending its participation in disarmament talks.

(8) On May 25, 2009, the Government of North Korea conducted a second illegal nuclear test, in addition to conducting tests of its ballistic missile systems.

(9) President Barack Obama stated that actions of the Government of North Korea ''are a matter of grave concern to all nations. North Korea's attempts to develop nuclear weapons, as well as its ballistic missile program, constitute a threat to international peace and security. By acting in blatant defiance of the United Nations Security Council, North Korea is directly and recklessly challenging the international community. North Korea's behavior increases tensions and undermines stability in Northeast Asia. Such provocations will only serve to deepen North Korea's isolation. It will not find international acceptance unless it abandons its

pursuit of weapons of mass destruction and their means of delivery.''

SEC. 102. DESIGNATION AS A COUNTRY THAT HAS REPEATEDLY PROVIDED SUPPORT FOR ACTS OF INTERNATIONAL TERRORISM.

(a) DESIGNATION.—The Secretary of State shall designate the Democratic People's Republic of North Korea as a country that has repeatedly provided support for acts of international terrorism for purposes of section 6(j) of the Export Administration Act of 1979 (50 U.S.C. App. 2405(j)), section 40 of the Arms Export Control Act (22 U.S.C. 2780), and section 620A of the Foreign Assistance Act of 1961 (22 U.S.C. 2371).

(b) WAIVER AUTHORITY.—The President may waive the requirements under subsection (a) upon certifying to Congress that the Government of North Korea has—

(1) verifiably dismantled its nuclear weapons programs;

(2) ceased all nuclear and missile proliferation activities;

(3) released United States citizens Euna Lee and Laura Ling;

(4) returned the last remains of United States permanent resident, Reverend Kim Dong-shik;

(5) released, or accounted for, all foreign abductees and prisoners of war; and

(6) released all North Korean prisoners of conscience.

SA 1242. Mr. BAYH (for himself, Ms. MURKOWSKI, Mr. BURRIS, Mr. LIEBERMAN, Mr. WARNER, Mr. WEBB, and Mr. NELSON of Nebraska) submitted an amendment intended to be proposed by him to the bill H.R. 1256, to protect the public health by providing the Food and Drug Administration with certain authority to regulate tobacco products, to amend title 5, United States Code, to make certain modifications in the Thrift Savings Plan, the Civil Service Retirement System, and the Federal Employees' Retirement System, and for other purposes; which was ordered to lie on the table; as follows:

At the end of the bill, add the following:

DIVISION __—NURSE FACULTY LOAN REPAYMENT PROGRAM

SEC. 1. SHORT TITLE.

This division may be cited as the ''Nurses' Higher Education and Loan Repayment Act of 2009''.

SEC. 2. FINDINGS.

The Congress finds the following:

(1) The Health Resources and Services Administration estimates there is currently a shortage of more than 200,000 registered nurses nationwide and projects the shortage will grow to more than 1,000,000 nurses by 2020, 36 percent less than needed to meet demand for nursing care.

(2) The shortage of qualified nursing faculty is the primary factor driving the inability of nursing schools to graduate more registered nurses to meet the Nation's growing workforce demand.

(3) There continues to be strong interest on the part of young Americans to enter the nursing field. The National League for Nursing estimates that 88,000 qualified applications, or 1 out of every 3 submitted to basic registered nurse programs in 2006, were rejected due to lack of capacity.

(4) The American Association of Colleges of Nursing (in this section referred to as the ''AACN'') estimates that 49,948 applicants were turned away specifically from baccalaureate and graduate schools of nursing in 2008 and over 70 percent of the schools responding to the AACN survey reported a lack of nurse faculty as the number 1 reason for turning away qualified applicants. Likewise, nearly 70 percent of the associate's degree registered nurse programs responding to the most recent American Association of Community Colleges Nursing Survey reported a lack of faculty to teach as the number 1 reason for turning away qualified applicants.

(5) Large numbers of faculty members at schools of nursing in the United States are nearing retirement. According to the AACN, the average age of a nurse faculty member is 55 years old and the average age at retirement is 62.

(6) The current nationwide nurse faculty vacancy rate is estimated to be as high as 7.6 percent, including 814 vacant positions at schools of nursing offering baccalaureate and advanced degrees and, in 2006, as many as 880 in associate's degree programs.

(7) Market forces have created disincentives for individuals qualified to become nurse educators from pursing this career. The average annual salary for an associate professor of nursing with a master's degree is nearly 20 percent less than the average salary for a nurse practitioner with a master's degree, according to the 2007 salary survey by the journal ADVANCE for Nurse Practitioners.

(8) The most recent Health Resources and Services Administration survey data indicates that from a total of more than 2,000,000 registered nurses, only 143,113 registered nurses with a bachelor's degree and only 51,318 registered nurses with an associate's degree have continued their education to earn a master's degree in the science of nursing, the minimum credential necessary to teach in all types of registered nurse programs. The majority of these graduates do not become nurse educators.

(9) Current Federal incentive programs to encourage nurses to become educators are inadequate and inaccessible for many interested nurses.

(10) A broad incentive program must be available to willing and qualified nurses that will provide financial support and encourage them to pursue and maintain a career in nursing education.

SEC. 3. NURSE FACULTY LOAN REPAYMENT PROGRAM.

Part E of title VIII of the Public Health Service Act (42 U.S.C. 297a et seq.) is amended by inserting after section 846A the following new section:

''SEC. 846B. NURSE FACULTY LOAN REPAYMENT PROGRAM.

''(a) ESTABLISHMENT.—The Secretary, acting through the Administrator of the Health Resources and Services Administration, may enter into an agreement with eligible individuals for the repayment of education loans, in accordance with this section, to increase the number of qualified nursing faculty.

''(b) AGREEMENTS.—Each agreement entered into under subsection (a) shall require that the eligible individual shall serve as a full-time member of the faculty of an accredited school of nursing for a total period, in the aggregate, of at least 4 years during the 6-year period beginning on the later of—

''(1) the date on which the individual receives a master's or doctorate nursing degree from an accredited school of nursing; or

''(2) the date on which the individual enters into an agreement under subsection (a).

''(c) AGREEMENT PROVISIONS.—Agreements entered into pursuant to subsection (a) shall be entered into on such terms and conditions as the Secretary may determine, except that—

''(1) not more than 300 days after the date on which the 6-year period described under subsection (b) begins, but in no case before the individual starts as a full-time member of the faculty of an accredited school of nursing, the Secretary shall begin making payments, for and on behalf of that individual, on the outstanding principal of, and interest on, any loan the individual obtained to pay for such degree;

''(2) for an individual who has completed a master's degree in nursing—

''(A) payments may not exceed $10,000 per calendar year; and

''(B) total payments may not exceed $40,000; and

''(3) for an individual who has completed a doctorate degree in nursing—

''(A) payments may not exceed $20,000 per calendar year; and

''(B) total payments may not exceed $80,000.

''(d) BREACH OF AGREEMENT.—

''(1) IN GENERAL.—In the case of any agreement made under subsection (a), the individual is liable to the Federal Government for the total amount paid by the Secretary under such agreement, and for interest on such amount at the maximum legal prevailing rate, if the individual fails to meet the agreement terms required under subsection (b).

''(2) WAIVER OR SUSPENSION OF LIABILITY.—In the case of an individual making an agreement for purposes of paragraph (1), the Secretary shall provide for the waiver or suspension of liability under such paragraph if compliance by the individual with the agreement involved is impossible or would involve extreme hardship to the individual or if enforcement of the agreement with respect to the individual would be unconscionable.

''(3) DATE CERTAIN FOR RECOVERY.—Subject to paragraph (2), any amount that the Federal Government is entitled to recover under paragraph (1) shall be paid to the United States not later than the expiration of the 3-year period beginning on the date the United States becomes so entitled.

''(4) AVAILABILITY.—Amounts recovered under paragraph (1) shall be available to the Secretary for making loan repayments under this section and shall remain available for such purpose until expended.

''(e) ELIGIBLE INDIVIDUAL DEFINED.—For purposes of this section, the term 'eligible individual' means an individual who—

''(1) is a United States citizen, national, or lawful permanent resident;

''(2) holds an unencumbered license as a registered nurse; and

''(3) has either already completed a master's or doctorate nursing program at an accredited school of nursing or is currently enrolled on a full-time or part-time basis in such a program.

''(f) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated to the Secretary such sums as may be necessary for each of fiscal years 2010 through 2014 to carry out this Act. Such sums shall remain available until expended.

''(g) SUNSET.—The provisions of this section shall terminate on December 31, 2020.''.

SA 1243. Mr. DEMINT (for himself, Mr. KYL, Mr. BUNNING, Mr. MARTINEZ, Mr. JOHANNS, Mr. RISCH, Mr. CRAPO, Mr. MCCONNELL, Mr. BOND, Mr. CORNYN, Mr. CHAMBLISS, Mr. COBURN, Mr. ROBERTS, Mr. INHOFE, Mr. BENNETT, Mr. BURR, and Mr. BROWNBACK) submitted an amendment intended to be proposed by him to the bill H.R. 1256, to protect the public health by providing the Food and Drug Administration with certain authority to regulate tobacco products, to amend title 5,

United States Code, to make certain modifications in the Thrift Savings Plan, the Civil Service Retirement System, and the Federal Employees' Retirement System, and for other purposes; which was ordered to lie on the table; as follows:

At the appropriate place, insert the following:

SEC. ___. STATE-SPONSOR OF TERRORISM.

The Secretary of State shall consider the Government of the Democratic People's Republic of Korea to have repeatedly provided support for acts of international terrorism, and the Democratic People's Republic of Korea shall be subject to the provisions set forth in section 40(d) of the Arms Export Control Act (22 U.S.C. 2780(d)), section 620A(a) of the Foreign Assistance Act of 1961 (22 U.S.C. 2371(a)), and section 6(j) of the Export Administration Act of 1979 (50 App. U.S.C. 2405(j)).

SA 1244. Mr. BURR (for himself and Mrs. HAGAN) submitted an amendment intended to be proposed by him to the bill H.R. 1256, to protect the public health by providing the Food and Drug Administration with certain authority to regulate tobacco products, to amend title 5, United States Code, to make certain modifications in the Thrift Savings Plan, the Civil Service Retirement System, and the Federal Employees' Retirement System, and for other purposes; which was ordered to lie on the table; as follows:

Strike all after the enacting clause and insert the following:

SECTION 1. SHORT TITLE; TABLE OF CONTENTS.

(a) SHORT TITLE.—This Act may be cited as the ''Preventing Disease and Death from Tobacco Use Act''.

(b) TABLE OF CONTENTS.—The table of contents of this Act is as follows:

SEC. 2. FINDINGS.

The Congress finds the following:

(1) Cigarette smoking is a leading cause of preventable deaths in the United States. Cigarette smoking significantly increases the risk of developing lung cancer, heart disease, chronic bronchitis, emphysema and other serious diseases with adverse health conditions.

(2) The risk for serious diseases is significantly affected by the type of tobacco product and the frequency, duration and manner of use.

(3) No tobacco product has been shown to be safe and without risks. The health risks associated with cigarettes are significantly greater than those associated with the use of smoke-free tobacco and nicotine products.

(4) Nicotine in tobacco products is addictive but is not considered a significant threat to health.

(5) It is the smoke inhaled from burning tobacco which poses the most significant risk of serious diseases.

(6) Quitting cigarette smoking significantly reduces the risk for serious diseases.

(7) Adult tobacco consumers have a right to be fully and accurately informed about the risks of serious diseases, the significant differences in the comparative risks of different tobacco and nicotine-based products, and the benefits of quitting. This information should be based on sound science.

(8) Governments, public health officials, tobacco manufacturers and others share a responsibility to provide adult tobacco consumers with accurate information about the various health risks and comparative risks associated with the use of different tobacco and nicotine products.

(9) Tobacco products should be regulated in a manner that is designed to achieve significant and measurable reductions in the morbidity and mortality associated with tobacco use. Regulations should enhance the information available to adult consumers to permit them to make informed choices, and encourage the development of tobacco and nicotine products with lower risks than cigarettes currently sold in the United States.

(10) The form of regulation should be based on the risks and comparative risks of tobacco and nicotine products and their respective product categories.

(11) The regulation of marketing of tobacco products should be consistent with constitutional protections and enhance an adult consumer's ability to make an informed choice by providing accurate information on the risks and comparative risks of tobacco products.

(12) Reducing the diseases and deaths associated with the use of cigarettes serves public health goals and is in the best interest of consumers and society. Harm reduction should be the critical element of any comprehensive public policy surrounding the health consequences of tobacco use.

(13) Significant reductions in the harm associated with the use of cigarettes can be achieved by providing accurate information regarding the comparative risks of tobacco products to adult tobacco consumers, thereby encouraging smokers to migrate to the use of smoke-free tobacco and nicotine products, and by developing new smoke-free tobacco and nicotine products and other actions.

(14) Governments, public health officials, manufacturers, tobacco producers and consumers should support the development, production, and commercial introduction of tobacco leaf, and tobacco and nicotine-based products that are scientifically shown to reduce the risks associated with the use of existing tobacco products, particularly cigarettes.

(15) Adult tobacco consumers should have access to a range of commercially viable tobacco and nicotine-based products.

(16) There is substantial scientific evidence that selected smokeless tobacco products can satisfy the nicotine addiction of inveterate smokers while eliminating most, if not all, risk of pulmonary and cardiovascular complications of smoking and while reducing the risk of cancer by more than 95 percent.

(17) Transitioning smokers to selected smokeless tobacco products will eliminate environmental tobacco smoke and fire-related hazards.

(18) Current ''abstain, quit, or die'' tobacco control policies in the United States may have reached their maximum possible public health benefit because of the large number of cigarette smokers either unwilling or unable to discontinue their addiction to nicotine.

(19) There is evidence that harm reduction works and can be accomplished in a way that will not increase initiation or impede smoking cessation.

(20) Health-related agencies and organizations, both within the United States and abroad have already gone on record endorsing Harm Reduction as an approach to further reducing tobacco related illness and death.

(21) Current Federal policy requires tobacco product labeling that leaves the incorrect impression that all tobacco product present equal risk.

SEC. 3. PURPOSE.

The purposes of this Act are—

(1) to provide authority to the Tobacco Harm Reduction Center by recognizing it as the primary Federal regulatory authority with respect to tobacco products as provided for in this Act;

(2) to ensure that the Center has the authority to address issues of particular concern to public health officials, especially the use of tobacco by young people and dependence on tobacco;

(3) to authorize the Center to set national standards controlling the manufacture of tobacco products and the identity, public disclosure, and amount of ingredients used in such products;

(4) to provide new and flexible enforcement authority to ensure that there is effective oversight of the tobacco industry's efforts to develop, introduce, and promote less harmful tobacco products;

(5) to vest the Center with the authority to regulate the levels of tar, nicotine, and other harmful components of tobacco products;

(6) to ensure that consumers are better informed regarding the relative risks for death and disease between categories of tobacco products;

(7) to continue to allow the sale of tobacco products to adults in conjunction with measures to ensure that they are not sold or accessible to underage purchasers;

(8) to impose appropriate regulatory controls on the tobacco industry;

(9) to promote prevention, cessation, and harm reduction policies and regulations to reduce disease risk and the social costs associated with tobacco-related diseases;

(10) to provide authority to the Department of Health and Human Services to regulate tobacco products;

(11) to establish national policies that effectively reduce disease and death associated with cigarette smoking and other tobacco use;

(12) to establish national policies that encourage prevention, cessation, and harm reduction measures regarding the use of tobacco products;

(13) to encourage current cigarette smokers who will not quit to use noncombustible tobacco or nicotine products that have significantly less risk than cigarettes;

(14) to establish national policies that accurately and consistently inform adult tobacco consumers of significant differences in risk between respective tobacco products;

(15) to establish national policies that encourage and assist the development and awareness of noncombustible tobacco and nicotine products;

(16) to coordinate national and State prevention, cessation, and harm reduction programs;

(17) to impose measures to ensure tobacco products are not sold or accessible to underage purchasers; and

(18) to strengthen Federal and State legislation to prevent illicit trade in tobacco products.

SEC. 4. SCOPE AND EFFECT.

(a) INTENDED EFFECT.—Nothing in this Act (or an amendment made by this Act) shall be construed to—

(1) establish a precedent with regard to any other industry, situation, circumstance, or legal action;

(2) affect any action pending in Federal, State, or Tribal court, or any agreement, consent decree, or contract of any kind; or

(3) be applicable to tobacco products or component parts manufactured in the United States for export.

(b) AGRICULTURAL ACTIVITIES.—The provisions of this Act (or an amendment made by this Act) which authorize the Administrator to take certain actions with regard to tobacco and tobacco products shall not be construed to affect any authority of the Secretary of Agriculture under existing law regarding the growing, cultivation, or curing of raw tobacco.

(c) REVENUE ACTIVITIES.—The provisions of this Act (or an amendment made by this Act) which authorize the Administrator to take certain actions with regard to tobacco products shall not be construed to affect any authority of the Secretary of the Treasury under chapter 52 of the Internal Revenue Code of 1986.

SEC. 5. SEVERABILITY.

If any provision of this Act, the amendments made by this Act, or the application of any provision of this Act to any person or circumstance is held to be invalid, the remainder of this Act, the amendments made by this Act, and the application of the provisions of this Act to any other person or circumstance shall not be affected and shall continue to be enforced to the fullest extent possible.

SEC. 6. EFFECTIVE DATE.

Except as otherwise specifically provided, the effective date of this Act shall be the date of its enactment.

TITLE I—AUTHORITY OF THE TOBACCO HARM REDUCTION CENTER

SEC. 100. DEFINITIONS.

In this Act:

(1) The term ''Administrator'' means the chief executive of the Tobacco Regulatory Agency (the Agency responsible for administering and enforcing this Act and regulations promulgated pursuant to this Act).

(2) The term ''adult'' means any individual who has attained the minimum age under applicable State law to be an individual to whom tobacco products may lawfully be sold.

(3) The term ''adult-only facility'' means a facility or restricted area, whether open-air or enclosed, where the operator ensures, or has a reasonable basis to believe, that no youth is present. A facility or restricted area need not be permanently restricted to adults in order to constitute an adult-only facility, if the operator ensures, or has a reasonable basis to believe, that no youth is present during any period of operation as an adult-only facility.

(4) The term ''advertising'' means a communication to the general public by a tobacco product manufacturer, distributor, retailer, or its agents, which identifies a tobacco product by brand name and is intended by such manufacturer, distributor, retailer, or its agents to promote purchases of such tobacco product. Such term shall not include—

(A) any advertising or other communication in any tobacco trade publication or tobacco trade promotional material;

(B) the content of any scientific publication or presentation, or any patent application or other communication to the United States Patent and Trademark Office or any similar office in any other country;

(C) any corporate or financial report or financial communication;

(D) any communication to a lending institution or to securities holders;

(E) any communication not intended for public display or public exposure, except that a direct mailing or direct electronic communication of what otherwise is advertising shall be deemed to be advertising;

(F) any communication in, on, or within a factory, office, plant, warehouse, or other facility related to or associated with the development, manufacture, or storage of tobacco products;

(G) any communication to any governmental agency, body, official, or employee;

(H) any communication to any journalist, editor, Internet blogger, or other author;

(I) any communication in connection with litigation, including arbitration and like proceedings; or

(J) any editorial advertisement that addresses a public issue.

(5) The term ''affiliate'' means a person that directly or indirectly owns or controls, is owned or controlled by, or is under common ownership or control with, another person. The terms ''owns,'' ''is owned'', and ''ownership'' refer to ownership of an equity interest, or the equivalent thereof, of 50 percent or more.

(6) The term ''Agency'' means the Tobacco Regulatory Agency.

(7) The term ''age-verified adult'' means any individual who is an adult and—

(A) who has stated or acknowledged, after being asked, that he or she is an adult and a tobacco product user, and has presented proof of age identifying the individual and verifying that the individual is an adult; or

(B) whose status as an adult has been verified by a commercially available database of such information.

(8) The term ''annual report'' means a tobacco product manufacturer's annual report to the Agency, which provides ingredient information and nicotine yield ratings for each brand style that tobacco product manufacturer manufactures for commercial distribution domestically.

(9) The term ''brand name'' means a brand name of a tobacco product distributed or sold domestically, alone, or in conjunction with any other word, trademark, logo, symbol, motto, selling message, recognizable pattern of colors, or any other indicium of product identification identical or similar to, or identifiable with, those used for any domestic brand of tobacco product. The term shall not include the corporate name of any tobacco product manufacturer that does not, after the effective date of this Act, sell a brand style of tobacco product in the United States that includes such corporate name.

(10) The term ''brand name sponsorship'' means an athletic, musical, artistic, or other social or cultural event, series, or tour, with respect to which payment is made, or other consideration is provided, in exchange for use of a brand name or names—

(A) as part of the name of the event; or

(B) to identify, advertise, or promote such event or an entrant, participant, or team in such event in any other way.

(11) The term ''brand style'' means a tobacco product having a brand name, and distinguished by the selection of the tobacco, ingredients, structural materials, format, configuration, size, package, product descriptor, amount of tobacco, or yield of ''tar'' or nicotine.

(12) The term ''carton'' means a container into which packages of tobacco products are directly placed for distribution or sale, but does not include cases intended for shipping. Such term includes a carton containing 10 packages of cigarettes.

(13) The term ''cartoon'' means any drawing or other depiction of an object, person, animal, creature or any similar caricature that satisfies any of the following criteria:

(A) The use of comically exaggerated features.

(B) The attribution of human characteristics to animals, plants or other objects, or

the similar use of anthropomorphic technique.

(C) The attribution of unnatural or extrahuman abilities, such as imperviousness to pain or injury, X-ray vision, tunneling at very high speeds, or transformation.

The term does not include any drawing or other depiction that, on the effective date of this Act, was in use in the United States in any tobacco product manufacturer's corporate logo or in any tobacco product manufacturer's tobacco product packaging.

(14) The term ''cigar'' has the meaning assigned that term by the Alcohol and Tobacco Tax and Trade Bureau in section 40.11 of title 27, Code of Federal Regulations.

(15) The term ''cigarette'' means—

(A) any roll of tobacco wrapped in paper or in any substance not containing tobacco; or

(B) any roll of tobacco wrapped in any substance containing tobacco which, because of the appearance of the roll of tobacco, the type of tobacco used in the filler, or its package or labeling, is likely to be offered to, or purchased by, consumers as a cigarette described in subparagraph (A).

(16) The term ''competent and reliable scientific evidence'' means evidence based on tests, analyses, research, or studies, conducted and evaluated in an objective manner by individuals qualified to do so, using procedures generally accepted in the relevant scientific disciplines to yield accurate and reliable results.

(17) The term ''distributor'' means any person who furthers the distribution of tobacco products, whether domestic or imported, at any point from the original place of manufacture to the person who sells or distributes the tobacco product to individuals for personal consumption. Common carriers, retailers, and those engaged solely in advertising are not considered distributors for purposes of this Act.

(18) The terms ''domestic'' and ''domestically'' mean within the United States, including activities within the United States involving advertising, marketing, distribution, or sale of tobacco products that are intended for consumption within the United States.

(19) The term ''human image'' means any photograph, drawing, silhouette, statue, model, video, likeness, or depiction of the appearance of a human being, or the appearance of any portion of the body of a human being.

(20) The term ''illicit tobacco product'' means any tobacco product intended for use by consumers in the United States—

(A) as to which not all applicable duties or taxes have been paid in full;

(B) that has been stolen, smuggled, or is otherwise contraband;

(C) that is counterfeit; or

(D) that has or had a label, labeling, or packaging stating, or that stated, that the product is or was for export only, or that it is or was at any time restricted by section 5704 of title 26, United States Code.

(21) The term ''illicit trade'' means any transfer, distribution, or sale in interstate commerce of any illicit tobacco product.

(22) The term ''immediate container'' does not include package liners.

(23) The term ''Indian tribe'' has the meaning assigned that term in section 4(e) of the Indian Self Determination and Education Assistance Act (25 U.S.C. 450b(e)).

(24) The term ''ingredient'' means tobacco and any substance added to tobacco to have an effect in the final tobacco product or when the final tobacco product is used by a consumer.

(25) The term ''International Organization for Standardization (ISO) testing regimen'' means the methods for measuring cigarette smoke yields, as set forth in the most recent version of ISO 3308, entitled ''Routine analytical cigarette-smoking machine—Definition of standard conditions''; ISO 4387, entitled ''Cigarettes—Determination of total and nicotine-free dry particulate matter using a routine analytical smoking machine''; ISO 10315, entitled ''Cigarettes—Determination of nicotine in smoke condensates—Gas-chromatographic method''; ISO 10362–1, entitled ''Cigarettes—Determination of water in smoke condensates—Part 1: Gas-chromatographic method''; and ISO 8454, entitled ''Cigarettes—Determination of carbon monoxide in the vapour phase of cigarette smoke—NDIR method''. A cigarette that does not burn down in accordance with the testing regimen standards may be measured under the same puff regimen using the number of puffs that such a cigarette delivers before it extinguishes, plus an additional three puffs, or with such other modifications as the Administrator may approve.

(26) The term ''interstate commerce'' means all trade, traffic, or other commerce—

(A) within the District of Columbia, or any territory or possession of the United States;

(B) between any point in a State and any point outside thereof;

(C) between points within the same State through any place outside such State; or

(D) over which the United States has jurisdiction.

(27) The term ''label'' means a display of written, printed, or graphic matter upon or applied securely to the immediate container of a tobacco product.

(28) The term ''labeling'' means all labels and other written, printed, or graphic matter (1) upon or applied securely to any tobacco product or any of its containers or wrappers, or (2) accompanying a tobacco product.

(29) The term ''little cigar'' has the meaning assigned that term by the Alcohol and Tobacco Tax and Trade Bureau in section 40.11 of title 27, Code of Federal Regulations.

(30) The term ''loose tobacco'' means any form of tobacco, alone or in combination with any other ingredient or material, that, because of its appearance, form, type, packaging, or labeling, is suitable for use and likely to be offered to, or purchased by, consumers as tobacco for making or assembling cigarettes, incorporation into pipes, or otherwise used by consumers to make any smoking article.

(31) The term ''manufacture'' means to design, manufacture, fabricate, assemble, process, package, or repackage, label, or relabel, import, or hold or store in a commercial quantity, but does not include—

(A) the growing, curing, de-stemming, or aging of tobacco; or

(B) the holding, storing or transporting of a tobacco product by a common carrier for hire, a public warehouse, a testing laboratory, a distributor, or a retailer.

(32) The term ''nicotine-containing product'' means a product intended for human consumption, other than a tobacco product, that contains added nicotine, whether or not in the form of a salt or solvate, that has been—

(A) synthetically produced, or

(B) obtained from tobacco or other source of nicotine.

(33) The term ''outdoor advertising''—

(A) except as provided in subparagraph (B), means—

(i) billboards;

(ii) signs and placards in arenas, stadiums, shopping malls, and video game arcades (whether any of such are open air or enclosed), but not including any such sign or placard located in an adult-only facility; and

(iii) any other advertisements placed outdoors; and

(B) does not include—

(i) an advertisement on the outside of a tobacco product manufacturing facility; or

(ii) an advertisement that—

(I) is inside a retail establishment that sells tobacco products (other than solely through a vending machine or vending machines);

(II) is placed on the inside surface of a window facing outward; and

(III) is no larger than 14 square feet.

(34) The term ''package'' means a pack, box, carton, pouch, or container of any kind in which a tobacco product or tobacco products are offered for sale, sold, or otherwise distributed to consumers. The term ''package'' does not include an outer container used solely for shipping one or more packages of a tobacco product or tobacco products.

(35) The term ''person'' means any individual, partnership, corporation, committee, association, organization or group of persons, or other legal or business entity.

(36) The term ''proof of age'' means a driver's license or other form of identification that is issued by a governmental authority and includes a photograph and a date of birth of the individual.

(37) The term ''raw tobacco'' means tobacco in a form that is received by a tobacco product manufacturer as an agricultural commodity, whether in a form that is—

(A) natural, stem or leaf;

(B) cured or aged; or (3)

(C) as parts or pieces, but not in a reconstituted form, extracted pulp form, or extract form.

(38) The term ''reduced-exposure claim'' means a statement in advertising or labeling intended for one or more consumers of tobacco products, that a tobacco product provides a reduced exposure of users of that tobacco product to one or more toxicants, as compared to an appropriate reference tobacco product or category of tobacco products. A statement or representation that a tobacco product or the tobacco in a tobacco product contains ''no additives'' or is ''natural'' or that uses a substantially similar term is not a reduced-exposure claim if the advertising or labeling that contains such statement or representation also contains the disclosure required by section 108(h) of this Act.

(39) The term ''reduced-risk claim'' means a statement in advertising or labeling intended for one or more consumers of tobacco products, that a tobacco product provides to users of that product a reduced risk of morbidity or mortality resulting from one or more chronic diseases or serious adverse health conditions associated with tobacco use, as compared to an appropriate reference tobacco product or category of tobacco products, even if it is not stated, represented, or implied that all health risks associated with using that tobacco product have been reduced or eliminated. A statement or representation that a tobacco product or the tobacco in a tobacco product contains ''no additives,'' or is ''natural,'' or that uses a substantially similar term is not a reduced-risk claim if the advertising or labeling that contains such statement or representation also contains the disclosure required by section 108(h).

(40) The term ''retailer'' means any person that—

(A) sells tobacco products to individuals for personal consumption; or

(B) operates a facility where the sale of tobacco products to individuals for personal consumption is permitted.

(41) The term ''sample'' means a tobacco product distributed to members of the public at no cost for the purpose of promoting the

product, but excludes tobacco products distributed—

(A) in conjunction with the sale of other tobacco products;

(B) for market research, medical or scientific study or testing, or teaching;

(C) to persons employed in the trade;

(D) to adult consumers in response to consumer complaints; or

(E) to employees of the manufacturer of the tobacco product.

(42) The term ''small business'' means a tobacco product manufacturer that—

(A) has 150 or fewer employees; and

(B) during the 3-year period prior to the current calendar year, had an average annual gross revenue from tobacco products that did not exceed $40,000,000.

(43) The term ''smokeless tobacco product'' means any form of finely cut, ground, powdered, reconstituted, processed or shaped tobacco, leaf tobacco, or stem tobacco, whether or not combined with any other ingredient, whether or not in extract or extracted form, and whether or not incorporated within any carrier or construct, that is intended to be placed in the oral or nasal cavity, including dry snuff, moist snuff, and chewing tobacco.

(44) The term ''smoking article'' means any tobacco-containing article that is intended, when used by a consumer, to be burned or otherwise to employ heat to produce a vapor, aerosol or smoke that—

(A) incorporates components of tobacco or derived from tobacco; and

(B) is intended to be inhaled by the user.

(45) The term ''State'' means any State of the United States and, except as otherwise specifically provided, includes any Indian tribe or tribal organization, the District of Columbia, the Commonwealth of Puerto Rico, Guam, the Virgin Islands, American Samoa, Wake Island, Midway Island, Kingman Reef, Johnston Atoll, the Northern Marianas, and any other trust territory or possession of the United States.

(46) The term ''tar'' means nicotine-free dry particulate matter as defined in ISO 4387, entitled ''Cigarettes—Determination of total and nicotine-free dry particulate matter using a routine analytical smoking machine''.

(47) The term ''tobacco'' means a tobacco plant or any part of a harvested tobacco plant intended for use in the production of a tobacco product, including leaf, lamina, stem, or stalk, whether in green, cured, or aged form, whether in raw, treated, or processed form, and whether or not combined with other materials, including any by-product, extract, extracted pulp material, or any other material (other than purified nicotine) derived from a tobacco plant or any component thereof, and including strip, filler, stem, powder, and granulated, blended, or reconstituted forms of tobacco.

(48) The term ''tobacco product'' means—

(A) the singular of ''tobacco products'' as defined in section 5702(c) of the Internal Revenue Code of 1986;

(B) any other product that contains tobacco as a principal ingredient and that, because of its appearance, type, or the tobacco used in the product, or its packaging and labeling, is likely to be offered to, or purchased by, consumers as a tobacco product as described in subparagraph (A); and

(C) any form of tobacco or any construct incorporating tobacco, intended for human consumption, whether by—

(i) placement in the oral or nasal cavity;

(ii) inhalation of vapor, aerosol, or smoke; or

(iii) any other means.

(49) The term ''tobacco product category'' means a type of tobacco product characterized by its composition, components, and intended use, and includes tobacco products classified as cigarettes, loose tobacco for roll-your-own tobacco products, little cigars, cigars, pipe tobacco, moist snuff, dry snuff, chewing tobacco, and other forms of tobacco products (which are treated in this Act collectively as a single category).

(50) The term ''tobacco product communication'' means any means, medium, or manner for providing information relating to any tobacco product, including face-to-face interaction, mailings by postal service or courier to an individual who is an addressee, and electronic mail to an individual who is an addressee.

(51) The term ''tobacco product manufacturer'' means an entity that directly—

(A) manufactures anywhere a tobacco product that is intended to be distributed commercially in the United States, including a tobacco product intended to be distributed commercially in the United States through an importer;

(B) is the first purchaser for resale in the United States of tobacco products manufactured outside the United States for distribution commercially in the United States; or

(C) is a successor or assign of any of the foregoing.

(52) The term ''toxicant'' means a chemical or physical agent that produces an adverse biological effect.

(53) The term ''transit advertisements'' means advertising on or within private or public vehicles and all advertisements placed at, on, or within any bus stop, taxi stand, transportation waiting area, train station, airport, or any similar location.

(54) The term ''tribal organization'' has the meaning assigned that term in section 4(1) of the Indian Self Determination and Education Assistance Act (25 U.S.C. 450b(1)).

(55) The term ''United States'' means the several States, as defined in this Act.

(56) The term ''vending machine'' means any mechanical, electric, or electronic self-service device that, upon insertion of money, tokens, or any other form of payment, automatically dispenses tobacco products.

(57) The term ''video game arcade'' means an entertainment establishment primarily consisting of video games (other than video games intended primarily for use by adults) or pinball machines.

(58) The term ''youth'' means any individual who in not an adult.

SEC. 101. CENTER AUTHORITY OVER TOBACCO PRODUCTS.

(a) IN GENERAL.—Tobacco products, including modified risk tobacco products for which an order has been issued in accordance with section 117, shall be regulated by the Administrator under this Act.

(b) APPLICABILITY.—This Act shall apply to all cigarettes, cigarette tobacco, roll-your-own tobacco, and smokeless tobacco and to any other tobacco products that the Administrator by regulation deems to be subject to this Act.

(c) CENTER.—The Secretary of Health and Human Services shall establish within the Department of Health and Human Services the Tobacco Harm Reduction Center. The head of the Center shall be an Administrator, who shall assume the statutory authority conferred by this Act, perform the functions that relate to the subject matter of this Act, and have the authority to promulgate regulations for the efficient enforcement of this Act. In promulgating any regulations under such authority, in whole or in part or any regulation that is likely to have an annual effect on the economy of $50,000,000 or more or have a material adverse effect on adult users of tobacco products, tobacco product manufacturers, distributors, or retailers, the Administrator shall—

(1) determine the technological and economic ability of parties that would be required to comply with the regulation to comply with it;

(2) consider experience gained under any relevantly similar regulations at the Federal or State level;

(3) determine the reasonableness of the relationship between the costs of complying with such regulation and the public health benefits to be achieved by such regulation;

(4) determine the reasonable likelihood of measurable and substantial reductions in morbidity and mortality among individual tobacco users;

(5) determine the impact to United States tobacco producers and farm operations;

(6) determine the impact on the availability and use of tobacco products by minors; and

(7) determine the impact on illicit trade of tobacco products.

(d) LIMITATION OF AUTHORITY.—

(1) IN GENERAL.—The provisions of this Act shall not apply to tobacco leaf that is not in the possession of a manufacturer of tobacco products, or to the producers of tobacco leaf, including tobacco growers, tobacco warehouses, and tobacco grower cooperatives, nor shall any employee of the Center have any authority to enter onto a farm owned by a producer of tobacco leaf without the written consent of such producer.

(2) EXCEPTION.—Notwithstanding paragraph (1), if a producer of tobacco leaf is also a tobacco product manufacturer or controlled by a tobacco product manufacturer, the producer shall be subject to this Act in the producer's capacity as a manufacturer. The exception in this subparagraph shall not apply to a producer of tobacco leaf who grows tobacco under a contract with a tobacco product manufacturer and who is not otherwise engaged in the manufacturing process.

(3) RULE OF CONSTRUCTION.—Nothing in this Act shall be construed to grant the Administrator authority to promulgate regulations on any matter that involves the production of tobacco leaf or a producer thereof.

(e) RULEMAKING PROCEDURES.—Each rulemaking under this Act shall be in accordance with chapter 5 of title 5, United States Code.

(f) CONSULTATION PRIOR TO RULEMAKING.—Prior to promulgating rules under this Act, the Administrator shall endeavor to consult with other Federal agencies as appropriate.

SEC. 102. EXCLUSION OF OTHER REGULATORY PROGRAMS.

(a) EXCLUSION OF TOBACCO PRODUCTS AND NICOTINE-CONTAINING PRODUCTS FROM THE FEDERAL FOOD, DRUG, AND COSMETIC ACT.—No tobacco product and no nicotine-containing product shall be regulated as a food, drug, or device in accordance with section 201 (f), (g) or (h) or Chapter IV or V of the Federal Food, Drug, and Cosmetic Act, except that any tobacco product commercially distributed domestically and any nicotine-containing product commercially distributed domestically shall be subject to Chapter V of the Federal Food, Drug, and Cosmetic Act if the manufacturer or a distributor of such product markets it with an explicit claim that the product is intended for use in the cure, mitigation, treatment, or prevention of disease in man or other animals, within the meaning of section 201(g)(1)(C) or section 201(h)(2) of that Act.

(b) LIMITATION ON EFFECT OF THIS ACT.—Nothing in this Act shall be construed to—

(1) establish a precedent with regard to any other industry, situation, circumstance, or legal action; or

(2) affect any action pending in any Federal, State, or Tribal court, or any agreement, consent decree, or contract of any kind.

(c) EXCLUSIONS FROM AUTHORITY OF ADMINISTRATOR.—The authority granted to the Administrator under this Act shall not apply to—

(1) raw tobacco that is not in the possession or control of a tobacco product manufacturer;

(2) raw tobacco that is grown for a tobacco product manufacturer by a grower, and that is in the possession of that grower or of a person that is not a tobacco product manufacturer and is within the scope of subparagraphs (A) through(F) of paragraph (3); or

(3) the activities, materials, facilities, or practices of persons that are not tobacco product manufacturers and that are—

(A) producers of raw tobacco, including tobacco growers;

(B) tobacco warehouses, and other persons that receive raw tobacco from growers;

(C) tobacco grower cooperatives;

(D) persons that cure raw tobacco;

(E) persons that process raw tobacco; and

(F) persons that store raw tobacco for aging.

If a producer of raw tobacco is also a tobacco product manufacturer, an affiliate of a tobacco product manufacturer, or a person producing raw tobacco for a tobacco product manufacturer, then that producer shall be subject to this Act only to the extent of that producer's capacity as a tobacco product manufacturer.

SEC. 103. EXISTING FEDERAL STATUTES MAINTAINED.

Except as amended or repealed by this Act, all Federal statutes in effect as of the effective date of this Act that regulate tobacco, tobacco products, or tobacco product manufacturers shall remain in full force and effect. Such statutes include, without limitation—

(1) the Federal Cigarette Labeling and Advertising Act, sections 1331–1340 of title 15, United States Code, except that section 1335 of title 15, United States Code, is repealed;

(2) the Comprehensive Smokeless Tobacco Health Education Act of 1986, sections 4401–4408 of title 15, United States Code, except that section 4402(f) of title 15, United States Code, is repealed;

(3) section 300x–26 of title 42, United States Code; and

(4) those statutes authorizing regulation of tobacco, tobacco products, or tobacco product manufacturers by the Federal Trade Commission, the Department of Agriculture, the Environmental Protection Agency, the Internal Revenue Service, and the Alcohol and Tobacco Tax and Trade Bureau of the Department of the Treasury.

SEC. 104. PROCEEDINGS IN THE NAME OF THE UNITED STATES; SUBPOENAS; PREEMPTION OF STATE AND LOCAL LAW; NO PRIVATE RIGHT OF ACTION.

In furtherance of this Act:

(1) All proceedings for the enforcement, or to restrain violations, of this Act shall be by and in the name of the United States. Subpoenas for witnesses who are required to attend a court of the United States, in any district, may run into any other district in any proceeding under this section. No State, or political subdivision thereof, may proceed or intervene in any Federal or State court under this Act or under any regulation promulgated under it, or allege any violation thereof except a violation by the Administrator. Nothing in this Act shall be construed to create a right of action by any private person for any violation of any provision of this Act or of any regulation promulgated under it.

(2) With respect to any subject matter addressed by this Act or by any regulation promulgated under it, no requirement or prohibition shall be imposed under State or local law upon any tobacco product manufacturer or distributor.

(3) Paragraph (2) shall not apply to any requirement or prohibition imposed under State or local law before the date of introduction of the bill that was enacted as this Act.

SEC. 105. ADULTERATED TOBACCO PRODUCTS.

A tobacco product shall be deemed to be adulterated—

(1) if it bears or contains any poisonous or deleterious substance other than—

(A) tobacco;

(B) a substance naturally present in tobacco;

(C) a pesticide or fungicide chemical residue in or on tobacco if such pesticide or fungicide chemical is registered by the Environmental Protection Agency for use on tobacco in the United States; or

(D) in the case of imported tobacco, a residue of a pesticide or fungicide chemical that—

(i) is approved for use in the country of origin of the tobacco; and

(ii) has not been banned, and the registration of which has not been canceled, by the Environmental Protection Agency for use on tobacco in the United States) that may render it injurious to health; but, in case the substance is not an added substance, such tobacco product shall not be considered adulterated under this subsection if the quantity of such substance in such tobacco product does not ordinarily render it injurious to health;

(2) if there is significant scientific agreement that, as a result of the tobacco it contains, the tobacco product presents a risk to human health that is materially higher than the risk presented by—

(A) such product on the effective date of this Act; or

(B) if such product was not distributed commercially domestically on that date, by comparable tobacco products of the same style and within the same category that were commercially distributed domestically on that date;

(3) if it has been prepared, packed, or held under unsanitary conditions whereby it may have become contaminated with filth;

(4) if its package is composed, in whole or in part, of any poisonous or deleterious substance that may render the contents injurious to health; or

(5) if its ''tar'' yield is in violation of section 111.

SEC. 106. MISBRANDED TOBACCO PRODUCTS.

A tobacco product shall be deemed to be misbranded—

(1) if its labeling is false or misleading in any particular;

(2) if in package form unless it bears a label containing—

(A) an identification of the type of product it is, by the common or usual name of such type of product;

(B) an accurate statement of the quantity of the contents in the package in terms of weight, measure, or numerical count, except that reasonable variations shall be permitted, and exemptions as to small packages shall be established by regulations promulgated by the Administrator;

(C) the name and place of business of the tobacco product manufacturer, packer, or distributor; and

(D) the information required by section 201(c) and (e) or section 202(c) and (e), as applicable;

(3) if any word, statement, or other information required by or under authority of this Act to appear on the label, labeling, or advertising is not prominently placed thereon with such conspicuousness (as compared with other words, statements, or designs on the label, labeling, or advertising, as applicable) and in such terms as to render it reasonably likely to be read and understood by the ordinary individual under customary conditions of purchase and use;

(4) if any word, statement, or other information is required by or under this Act to appear on the label, unless such word, statement, or other information also appears on the outside container or wrapper, if any, of the retail package of such tobacco product, or is easily legible through the outside container or wrapper;

(5) if it was manufactured, prepared, or processed in an establishment not duly registered under section 109, if it was not included in a list required by section 109, or if a notice or other information respecting it was not provided as required by section 109;

(6) if its packaging, labeling, or advertising is in violation of this Act or of an applicable regulation promulgated in accordance with this Act;

(7) if it contains tobacco or another ingredient as to which a required disclosure under this Act was not made;

(8) if it is labeled or advertised, or the tobacco contained in it is advertised, as—

(A) containing ''no additives,'' or any substantially similar term, unless the labeling or advertising, as applicable, also contains, clearly and prominently, the following disclosure: ''No additives in our tobacco does NOT mean safer.''; or

(B) being ''natural,'' or any substantially similar term, unless the labeling or advertising, as applicable, also contains, clearly and prominently, the following disclosure: ''Natural does NOT mean safer.'';

(9) if in its labeling or advertising a term descriptive of the tobacco in the tobacco product is used otherwise than in accordance with a sanction or approval granted by a Federal agency;

(10) if with respect to such tobacco product a disclosure required by section 603 was not made;

(11) if with respect to such tobacco product a certification required by section 803 was not submitted or is materially false or misleading; or

(12) if its manufacturer or distributor made with respect to it a claim prohibited by section 115.

SEC. 107. SUBMISSION OF HEALTH INFORMATION TO THE ADMINISTRATOR.

(a) REQUIREMENT.—Each tobacco product manufacturer or importer, or agents thereof, shall submit to the Administrator the following information:

(1) Not later than 18 months after the date of enactment of the Act, a listing of all ingredients, including tobacco, substances, compounds, and additives that are, as of such date, added by the manufacturer to the tobacco, paper, filter, or other part of each tobacco product by brand and by quantity in each brand and brand style.

(2) A description of the content, delivery, and form of nicotine in each tobacco product measured in milligrams of nicotine in accordance with regulations promulgated by the Administrator in accordance with section 4(e) of the Federal Cigarette Labeling and Advertising Act.

(3) Beginning 4 years after the date of enactment of this Act, a listing of all constituents, including smoke constituents as applicable, identified by the Administrator as harmful to health in each tobacco product, and as applicable in the smoke of each tobacco product, by brand and by quantity in each brand and subbrand.

(b) DATA SUBMISSION.—At the request of the Administrator, each tobacco product manufacturer or importer of tobacco products, or agents thereof, shall submit the following:

(1) Any or all documents (including underlying scientific information) relating to research activities, and research findings, conducted, supported, or possessed by the manufacturer (or agents thereof) on the health, toxicological, or physiologic effects of tobacco products and their constituents (including smoke constituents), ingredients, components, and additives.

(2) Any or all documents (including underlying scientific information) relating to research activities, and research findings, conducted, supported, or possessed by the manufacturer (or agents thereof) that relate to the issue of whether a significant reduction in risk to health from tobacco products can occur upon the employment of technology available to the manufacturer.

An importer of a tobacco product not manufactured in the United States shall supply the information required of a tobacco product manufacturer under this subsection.

(c) DATA LIST.—

(1) IN GENERAL.—Not later than 4 years after the date of enactment of the Act, and annually thereafter, the Administrator shall publish in a format that is understandable and not misleading to a lay person, and place on public display (in a manner determined by the Administrator) the list established under subsection (d).

(2) CONSUMER RESEARCH.—The Administrator shall conduct periodic consumer research to ensure that the list published under paragraph (1) is not misleading to lay persons. Not later than 5 years after the date of enactment of the Act, the Administrator shall submit to the appropriate committees of Congress a report on the results of such research, together with recommendations on whether such publication should be continued or modified.

(d) DATA COLLECTION.—Not later than 36 months after the date of enactment of this Act, the Administrator shall establish, and periodically revise as appropriate, a list of harmful constituents, including smoke constituents, to health in each tobacco product by brand and by quantity in each brand and subbrand.

SEC. 108. REGISTRATION AND LISTING.

(a) DEFINITIONS.—As used in this section:

(1) The term ''manufacture, preparation, or processing'' shall include repackaging or otherwise changing the container, wrapper, or label of any tobacco product package other than the carton in furtherance of the distribution of the tobacco product from the original place of manufacture to the person that makes final delivery or sale to the ultimate consumer or user, but shall not include the addition of a tax marking or other marking required by law to an already packaged tobacco product.

(2) The term ''name'' shall include in the case of a partnership the name of the general partner and, in the case of a privately held corporation, the name of the chief executive officer of the corporation and the State of incorporation.

(b) ANNUAL REGISTRATION.—Commencing one year after enactment, on or before December 31 of each year, every person that owns or operates any establishment in any State engaged in the manufacture, preparation, or processing of a tobacco product or products for commercial distribution domestically shall register with the Administrator its name, places of business, and all such establishments.

(c) NEW PRODUCERS.—Every person upon first engaging, for commercial distribution domestically, in the manufacture, preparation, or processing of a tobacco product or products in any establishment that it owns or operates in any State shall immediately register with the Administrator its name, places of business, and such establishment.

(d) REGISTRATION OF FOREIGN ESTABLISHMENTS.—

(1) Commencing one year after enactment of this Act, on or before December 31 of each year, the person that, within any foreign country, owns or operates any establishment engaged in the manufacture, preparation, or processing of a tobacco product that is imported or offered for import into the United States shall, through electronic means or other means permitted by the Administrator, register with the Administrator the name and place of business of each such establishment, the name of the United States agent for the establishment, and the name of each importer of such tobacco product in the United States that is known to such person.

(2) Such person also shall provide the information required by subsection (j), including sales made by mail, or through the Internet, or other electronic means.

(3) The Administrator is authorized to enter into cooperative arrangements with officials of foreign countries to ensure that adequate and effective means are available for purposes of determining, from time to time, whether tobacco products manufactured, prepared, or processed by an establishment described in paragraph (1), if imported or offered for import into the United States, shall be refused admission on any of the grounds set forth in section 708.

(e) ADDITIONAL ESTABLISHMENTS.—Every person duly registered in accordance with the foregoing subsections of this section shall immediately register with the Administrator any additional establishment that it owns or operates and in which it begins the manufacture, preparation, or processing of a tobacco product or products for commercial distribution domestically or for import into the United States.

(f) EXCLUSIONS FROM APPLICATION OF THIS SECTION.—The foregoing subsections of this section shall not apply to—

(1) persons that manufacture, prepare, or process tobacco products solely for use in research, teaching, chemical or biological analysis, or export; or

(2) such other classes of persons as the Administrator may by regulation exempt from the application of this section upon a finding that registration by such classes of persons in accordance with this section is not necessary for the protection of the public health.

(g) INSPECTION OF PREMISES.—Every establishment registered with the Administrator pursuant to this section shall be subject to inspection pursuant to section 706; and every such establishment engaged in the manufacture, preparation, or processing of a tobacco product or products shall be so inspected by one or more officers or employees duly designated by the Administrator at least once in the two-year period beginning with the date of registration of such establishment pursuant to this section and at least once in every successive two-year period thereafter, except that inspection of establishments outside the United States may be conducted by other personnel pursuant to a cooperative arrangement under subsection (d)(3).

(h) FILING OF LISTS OF TOBACCO PRODUCTS MANUFACTURED, PREPARED, OR PROCESSED BY REGISTRANTS; STATEMENTS; ACCOMPANYING DISCLOSURES.—

(1) Every person that registers with the Administrator under subsection (b), (c), (d), or (e) shall, at the time of registration under any such subsection, file with the Administrator a list of all brand styles (with each brand style in each list listed by the common or usual name of the tobacco product category to which it belongs and by any proprietary name) that are being manufactured, prepared, or processed by such person for commercial distribution domestically or for import into the United States, and that such person has not included in any list of tobacco products filed by such person with the Administrator under this paragraph or paragraph (2) before such time of registration. Such list shall be prepared in such form and manner as the Administrator may prescribe, and shall be accompanied by the label for each such brand style and a representative sampling of any other labeling and advertising for each;

(2) Each person that registers with the Administrator under this section shall report to the Administrator each August for the preceding six-month period from January through June, and each February for the preceding six-month period form July through December, following information:

(A) A list of each brand style introduced by the registrant for commercial distribution domestically or for import into the United States that has not been included in any list previously filed by such registrant with the Administrator under this subparagraph or paragraph (1). A list under this subparagraph shall list a brand style by the common or usual name of the tobacco product category to which it belongs and by any proprietary name, and shall be accompanied by the other information required by paragraph (1).

(B) If since the date the registrant last made a report under this paragraph (or if such registrant has not previously made a report under this paragraph, since the effective date of this Act) such registrant has discontinued the manufacture, preparation, or processing for commercial distribution domestically or for import into the United States of a brand style included in a list filed by such registrant under subparagraph (A) or paragraph (1), notice of such discontinuance, the date of such discontinuance, and the identity (by the common or usual name of the tobacco product category to which it belongs and by any proprietary name) of such tobacco product.

(C) If, since the date the registrant reported pursuant to subparagraph (B) a notice of discontinuance of a tobacco product, the registrant has resumed the manufacture, preparation, or processing for commercial distribution domestically or for import into the United States of that brand style, notice of such resumption, the date of such resumption, the identity of such brand style (by the common or usual name of the tobacco product category to which it belongs and by any proprietary name), and the other information required by paragraph (1), unless the registrant has previously reported such resumption to the Administrator pursuant to this subparagraph.

(D) Any material change in any information previously submitted pursuant to this paragraph (2) or paragraph (1).

(i) ELECTRONIC REGISTRATION.—Registrations under subsections (b), (c), (d), and (e) (including the submission of updated information) shall be submitted to the Administrator by electronic means, unless the Administrator grants a request for waiver of such requirement because use of electronic means is not reasonable for the person requesting such waiver.

SEC. 109. GENERAL PROVISIONS RESPECTING CONTROL OF TOBACCO PRODUCTS.

(a) IN GENERAL.—Any requirement established by or under section 106, 107, or 113 applicable to a tobacco product shall apply to such tobacco product until the applicability of the requirement to the tobacco product has been changed by action taken under section 111, section 114, section 115, or subsection (d) of this section, and any requirement established by or under section 106, 107, or 113 which is inconsistent with a requirement imposed on such tobacco product under

section 111, section 114, section 115, or subsection (d) of this section shall not apply to such tobacco product.

(b) INFORMATION ON PUBLIC ACCESS AND COMMENT.—Each notice of proposed rulemaking or other notification under section 111, 112, 113, 114, or 115 or under this section, any other notice which is published in the Federal Register with respect to any other action taken under any such section and which states the reasons for such action, and each publication of findings required to be made in connection with rulemaking under any such section shall set forth—

(1) the manner in which interested persons may examine data and other information on which the notice or findings is based; and

(2) the period within which interested persons may present their comments on the notice or findings (including the need therefore) orally or in writing, which period shall be at least 60 days but may not exceed 90 days unless the time is extended by the Administrator by a notice published in the Federal Register stating good cause therefore.

(c) LIMITED CONFIDENTIALITY OF INFORMATION.—Any information reported to or otherwise obtained by the Administrator or the Administrator's representative under section 107, 108, 111, 112, 113, 114, 115, or 504, or under subsection (e) or (f) of this section, which is exempt from disclosure under subsection (a) of section 552 of title 5, United States Code, by reason of subsection (b)(4) of that section shall be considered confidential and shall not be disclosed, except that the information may be disclosed to other officers or employees concerned with carrying out this Act, or when relevant in any proceeding under this Act.

(d) RESTRICTIONS.—

(1) IN GENERAL.—The Administrator may issue regulations, consistent with this Act, regarding tobacco products if the Administrator determines that such regulation would be appropriate for the protection of the public health. The finding as to whether such regulation would be appropriate for the protection of the public health shall be determined with respect to the risks and benefits to the users of the tobacco product, and taking into account that the standard is reasonably likely to result in measurable and substantial reductions in morbidly and mortality among individual tobacco users.

(2) LABEL STATEMENTS.—The label of a tobacco product shall bear such appropriate statements of the restrictions required by a regulation under subsection (a) as the Administrator may in such regulation prescribe.

(e) GOOD MANUFACTURING PRACTICE REQUIREMENTS.—

(1) METHODS, FACILITIES, AND CONTROLS TO CONFORM.—

(A) IN GENERAL.—In applying manufacturing restrictions to tobacco, the Administrator shall, in accordance with subparagraph (B), prescribe regulations (which may differ based on the type of tobacco product involved) requiring that the methods used in, and the facilities and controls used for, the manufacture, preproduction design validation (including a process to assess the performance of a tobacco product), packing, and storage of a tobacco product conform to current good manufacturing practice, or hazard analysis and critical control point methodology, as prescribed in such regulations to assure that the public health is protected and that the tobacco product is in compliance with this Act. Such regulations may provide for the testing of raw tobacco for pesticide chemical residues after a tolerance for such chemical residues has been established.

(B) REQUIREMENTS.—The Administrator shall—

(i) before promulgating any regulation under subparagraph (A), afford the Tobacco Products Scientific Advisory Committee an opportunity to submit recommendations with respect to the regulation proposed to be promulgated;

(ii) before promulgating any regulation under subparagraph (A), afford opportunity for an oral hearing;

(iii) provide the Tobacco Products Scientific Advisory Committee a reasonable time to make its recommendation with respect to proposed regulations under subparagraph (A); and

(iv) in establishing the effective date of a regulation promulgated under this subsection, take into account the differences in the manner in which the different types of tobacco products have historically been produced, the financial resources of the different tobacco product manufacturers, and the state of their existing manufacturing facilities, and shall provide for a reasonable period of time for such manufacturers to conform to good manufacturing practices but no earlier than four years from date of enactment.

(C) ADDITIONAL SPECIAL RULE.—A tobacco product manufactured in or imported into the United States shall not contain foreign-grown flue-cured or burley tobacco that—

(i) was knowingly grown or processed using a pesticide chemical that is not approved under applicable Federal law for use in domestic tobacco farming and processing; or

(ii) in the case of a pesticide chemical that is so approved, was grown or processed using the pesticide chemical in a manner inconsistent with the approved labeling for use of the pesticide chemical in domestic tobacco farming and processing.

(D) EXCLUSION.—Subparagraph (C)(ii) shall not apply to tobacco products manufactured with foreign-grown flue-cured or burley tobacco so long as that foreign grown tobacco was either—

(i) in the inventory of a manufacturer prior to the effective date, or

(ii) planted by the farmer prior to the effective date of this Act and utilized by the manufacturer no later than 3 years after the effective date.

(E) SETTING OF MAXIMUM RESIDUE LIMITS.—The Administrator shall adopt the following pesticide residue standards:

Pesticide residue standards

The maximum concentration of residues of the following pesticides allowed in flue-cured or burley tobacco, expressed as parts by weight of the residue per one million parts by weight of the tobacco (PPM) are:

CHLORDANE.....3.0

DIBROMOCHLOROPROPANE (DBCP).....1.0

DICAMBA (Temporary).... 5.0

ENDRIN....0.1

ETHYLENE DIBROMIDE (EDB)....0.1

FORMOTHION.....0.5

HEXACHLOROBENZENE (HCB)....0.1

METHOXYCHLOR.....0.1

TOXAPHENE.....0.3

2,4-D (Temporary).....5.0

2,4,5-T.....0.1

Sum of ALDRIN and DIELDRIN.....0.1

Sum of CYPERMETHRIN and PERMETHRIN (Temporary).....3.0

Sum of DDT, TDE (DDD), and DDE 0.4

Sum of HEPTACHLOR and HEPTACHLOR EPOXIDE.....0.1

(F) MAXIMUM RESIDUE LIMITS.—The Administrator shall adopt regulations within one year of the effective date of this Act to establish maximum residue limits for pesticides identified under subparagraph (E) but not included in the table of such subparagraph to account for the fact that weather and agronomic conditions will cause pesticides identified in subparagraph (E) to be detected in foreign-grown tobacco even where the farmer has not knowingly added such pesticide.

(2) EXEMPTIONS; VARIANCES.—

(A) PETITION.—Any person subject to any requirement prescribed under paragraph (1) may petition the Administrator for a permanent or temporary exemption or variance from such requirement. Such a petition shall be submitted to the Administrator in such form and manner as the Administrator shall prescribe and shall—

(i) in the case of a petition for an exemption from a requirement, set forth the basis for the petitioner's determination that compliance with the requirement is not required to assure that the tobacco product will be in compliance with this Act;

(ii) in the case of a petition for a variance from a requirement, set forth the methods proposed to be used in, and the facilities and controls proposed to be used for, the manufacture, packing, and storage of the tobacco product in lieu of the methods, facilities, and controls prescribed by the requirement; and

(iii) contain such other information as the Administrator shall prescribe.

(B) REFERRAL TO THE TOBACCO PRODUCTS SCIENTIFIC ADVISORY COMMITTEE.—The Administrator may refer to the Tobacco Products Scientific Advisory Committee any petition submitted under subparagraph (A). The Tobacco Products Scientific Advisory Committee shall report its recommendations to the Administrator with respect to a petition referred to it within 60 days after the date of the petition's referral. Within 60 days after—

(i) the date the petition was submitted to the Administrator under subparagraph (A); or

(ii) the day after the petition was referred to the Tobacco Products Scientific Advisory Committee,

whichever occurs later, the Administrator shall by order either deny the petition or approve it.

(C) APPROVAL.—The Administrator may approve—

(i) a petition for an exemption for a tobacco product from a requirement if the Administrator determines that compliance with such requirement is not required to assure that the tobacco product will be in compliance with this Act; and

(ii) a petition for a variance for a tobacco product from a requirement if the Administrator determines that the methods to be used in, and the facilities and controls to be used for, the manufacture, packing, and storage of the tobacco product in lieu of the methods, facilities, and controls prescribed by the requirement are sufficient to assure that the tobacco product will be in compliance with this Act.

(D) CONDITIONS.—An order of the Administrator approving a petition for a variance shall prescribe such conditions respecting the methods used in, and the facilities and controls used for, the manufacture, packing, and storage of the tobacco product to be granted the variance under the petition as may be necessary to assure that the tobacco product will be in compliance with this Act.

(E) HEARING.—After the issuance of an order under subparagraph (B) respecting a petition, the petitioner shall have an opportunity for an informal hearing on such order.

(3) COMPLIANCE.—Compliance with requirements under this subsection shall not be required before the end of the 3-year period following the date of enactment of this Act.

(f) RESEARCH AND DEVELOPMENT.—The Administrator may enter into contracts for research, testing, and demonstrations respecting tobacco products and may obtain tobacco products for research, testing, and demonstration purposes.

SEC. 110. SMOKING ARTICLE STANDARDS.

(a) IN GENERAL.—

(1) RESTRICTIONS ON DESCRIPTORS USED IN MARKETING OF CIGARETTES.—

(A) IN GENERAL.—Except as provided in subparagraph (B), no person shall use, with respect to any cigarette brand style commercially distributed domestically, on the portion of the package of such cigarette brand style that customarily is visible to consumers before purchase, or in advertising of such cigarette brand style any of the following as a descriptor of any cigarette brand style—

(i) the name of any candy or fruit;

(ii) the word ''candy,'' ''citrus,'' ''cream,'' ''fruit,'' ''sugar,'' ''sweet,'' ''tangy,'' or ''tart,''; or

(iii) any extension or variation of any of the words ''candy,'' ''citrus,'' ''cream,'' ''fruit,'' ''sugar,'' ''sweet,'' ''tangy,'' or ''tart,'' including but not limited to ''creamy,'' or ''fruity.''

(B) LIMITATION.—Subparagraph (A) shall not apply to the use of the following words or to any extension or variation of any of them: ''clove'' and ''menthol''.

(C) SCENTED MATERIALS.—No person shall use, in the advertising or labeling of any cigarette commercially distributed domestically, any scented materials, except in an adult-only facility.

(D) DEFINITIONS.—In this section:

(i) The term ''candy'' means a confection made from sugar or sugar substitute, including any confection identified generically or by brand, and shall include the words ''cacao,'' ''chocolate,'' ''cinnamon,'' ''cocoa,'' ''honey,'' ''licorice,'' ''maple,'' ''mocha,'' and ''vanilla.''

(ii) The term ''fruit'' means any fruit identified by generic name, type, or variety, including but not limited to ''apple,'' ''banana,'' ''cherry,'' and ''orange.'' The term ''fruit'' does not include words that identify seeds, nuts or peppers, or types or varieties thereof or words that are extensions or variations of such words.

(2) SMOKING ARTICLE STANDARDS.—

(A) IN GENERAL.—The Administrator may adopt smoking article standards in addition to those in paragraph (1) if the Administrator finds that a smoking article standard is appropriate for the protection of the public health.

(B) DETERMINATIONS.—

(i) CONSIDERATIONS.—In making a finding described in subparagraph (A), the Administrator shall consider scientific evidence concerning—

(I) the risks and benefits to the users of smoking articles of the proposed standard; and

(II) that the standard is reasonably likely to result in measurable and substantial reductions in morbidity and mortality among individual tobacco users.

(ii) ADDITIONAL CONSIDERATIONS.—In the event that the Administrator makes a determination, set forth in a proposed smoking article standard in a proposed rule, that it is appropriate for the protection of public health to require the reduction or elimination of an additive, constituent (including a smoke constituent), or other component of a smoking article because the Administrator has found that the additive, constituent, or other component is harmful, any party objecting to the proposed standard on the ground that the proposed standard will not reduce or eliminate the risk of illness or injury may provide for the Administrator's consideration scientific evidence that demonstrates that the proposed standard will not reduce or eliminate the risk of illness or injury.

(3) CONTENT OF SMOKING ARTICLE STANDARDS.—A smoking article standard established under this section for a smoking article—

(A) may include provisions that are appropriate for the protection of the public health, including provisions, where appropriate—

(i) for ''tar'' and nicotine yields of the product;

(ii) for the reduction of other constituents, including smoke constituents, or harmful components of the product; or

(iii) relating to any other requirement under subparagraph (B); and

(B) may, where appropriate for the protection of the public health, include—

(i) provisions respecting the construction, components, ingredients, additives, constituents, including smoke constituents, and properties of the smoking article;

(ii) provisions for the testing (on a sample basis or, if necessary, on an individual basis) of the smoking article;

(iii) provisions for the measurement of the smoking article characteristics of the smoking article; and

(iv) provisions requiring that the results of each or of certain of the tests of the smoking article required to be made under clause (ii) show that the smoking article is in conformity with the portions of the standard for which the test or tests were required.

(4) PERIODIC REEVALUATION OF SMOKING ARTICLE STANDARDS.—The Administrator may provide for periodic evaluation of smoking article standards established under this section to determine whether such standards should be changed to reflect new medical, scientific, or other technological data.

(5) CIGARETTE ''TAR'' LIMITS.—

(A) NO INCREASE IN ''TAR'' YIELDS.—No cigarette manufacturer shall distribute for sale domestically a brand style of cigarettes that generates a ''tar'' yield greater than the ''tar'' yield of that brand style of cigarettes on the date of introduction of this Act, as determined by the ISO smoking regimen and its associated tolerances. The ''tar'' tolerances for cigarettes with ISO ''tar'' yields in the range of 1 to 20 milligrams per cigarette, based on variations arising from sampling procedure, test method, and sampled product, itself, are the greater of plus or minus—

(i) 15 percent; or

(ii) 1 milligram per cigarette.

(B) LIMIT ON NEW CIGARETTES.—After the effective date of this Act, no cigarette manufacturer shall manufacture for commercial distribution domestically a brand style of cigarettes that both—

(i) was not in commercial distribution domestically on the effective date of this Act, and

(ii) generates a ''tar'' yield of greater than 20 milligrams per cigarette as determined by the ISO smoking regimen and its associated tolerances.

(C) LIMIT ON ALL CIGARETTES.—After December 31, 2010, no cigarette manufacturer shall manufacture for commercial distribution domestically a brand style of cigarettes that generates a ''tar'' yield greater than 20 milligrams per cigarette as determined by the ISO smoking regimen and its associated tolerances.

(D) REVIEW BY ADMINISTRATOR.—After the effective date of this Act, the Administrator shall evaluate the available scientific evidence addressing the potential relationship between historical ''tar'' yield values and risk of harm to smokers. If upon a review of that evidence, and after consultation with technical experts of the Tobacco Harm Reduction Center and the Centers for Disease Control and Prevention and notice and an opportunity for public comment, the Administrator determines, that a reduction in ''tar'' yield may reasonably be expected to provide a meaningful reduction of the risk or risks of harm to smokers, the Administrator shall issue an order that—

(i) provides that no cigarette manufacturer shall manufacture for commercial distribution domestically a cigarette that generates a ''tar'' yield that exceeds 14 milligrams as determined by the ISO smoking regimen and its associated tolerances; and

(ii) provides a reasonable time for manufacturers to come into compliance with such prohibition.

(6) INVOLVEMENT OF OTHER AGENCIES; INFORMED PERSONS.—In carrying out duties under this section, the Administrator shall endeavor to—

(A) use personnel, facilities, and other technical support available in other Federal agencies;

(B) consult with other Federal agencies concerned with standard setting and other nationally or internationally recognized standard-setting entities; and

(C) invite appropriate participation, through joint or other conferences, workshops, or other means, by informed persons representative of scientific, professional, industry, agricultural, or consumer organizations who in the Administrator's judgment can make a significant contribution.

(b) CONSIDERATIONS BY ADMINISTRATOR.—

(1) TECHNICAL ACHIEVABILITY.—The Administrator shall consider information submitted in connection with a proposed standard regarding the technical achievability of compliance with such standard.

(2) OTHER CONSIDERATIONS.—The Administrator shall consider all other information submitted in connection with a proposed standard, such as the creation of a significant demand for contraband or other tobacco products that do not meet the requirements of this Act and the significance of such demand.

(c) PROPOSED STANDARDS.—

(1) IN GENERAL.—The Administrator shall publish in the Federal Register a notice of proposed rulemaking for the establishment, amendment, or revocation of any smoking article standard.

(2) REQUIREMENTS OF NOTICE.—A notice of proposed rulemaking for the establishment or amendment of a smoking article standard shall—

(A) set forth a finding with supporting justification that the smoking article standard is appropriate for the protection of the public health;

(B) invite interested persons to submit a draft or proposed smoking article standard for consideration by the Administrator;

(C) invite interested persons to submit comments on structuring the standard so that it does not advantage foreign-grown tobacco over domestically grown tobacco; and

(D) invite the Secretary of Agriculture to provide any information or analysis which the Secretary of Agriculture believes is relevant to the proposed smoking article standard.

(3) FINDING.—A notice of proposed rulemaking for the revocation of a smoking article standard shall set forth a finding with supporting justification that the smoking article standard is no longer appropriate for the protection of the public health.

(4) COMMENT.—The Administrator shall provide for a comment period of not less than 90 days.

(d) PROMULGATION.—

(1) IN GENERAL.—After the expiration of the period for comment on a notice of proposed rulemaking published under subsection (c) respecting a standard and after consideration of comments submitted under subsections (b) and (c) and any report from the Tobacco Products Scientific Advisory Committee, if the Administrator determines that the standard would be appropriate for the

protection of the public health, the Administrator shall—

(A) promulgate a regulation establishing a smoking article standard and publish in the Federal Register findings on the matters referred to in subsection (c); or

(B) publish a notice terminating the proceeding for the development of the standard together with the reasons for such termination.

(2) EFFECTIVE DATE.—A regulation establishing a smoking article standard shall set forth the date or dates upon which the standard shall take effect, but no such regulation may take effect before 1 year after the date of its publication unless the Administrator determines that an earlier effective date is necessary for the protection of the public health. Such date or dates shall be established so as to minimize, consistent with the public health, economic loss to, and disruption or dislocation of, domestic and international trade. In establishing such effective date or dates, the Administrator shall consider information submitted in connection with a proposed product standard by interested parties, including manufacturers and tobacco growers, regarding the technical achievability of compliance with the standard, and including information concerning the existence of patents that make it impossible to comply in the timeframe envisioned in the proposed standard.

(3) LIMITATION ON POWER GRANTED.—Because of the importance of a decision of the Administrator to issue a regulation—

(A) banning cigarettes, smokeless smoking articles, little cigars, cigars other than little cigars, pipe tobacco, or roll-your-own smoking articles;

(B) requiring the reduction of ''tar'' or nicotine yields of a smoking article to zero;

(C) prohibiting the sale of any smoking article in face-to-face transactions by a specific category of retail outlets;

(D) establishing a minimum age of sale of smoking articles to any person older than 18 years of age; or

(E) requiring that the sale or distribution of a smoking article be limited to the written or oral authorization of a practitioner licensed by law to prescribe medical products,

the Administrator is prohibited from taking such actions under this Act.

(4) MATCHBOOKS.—For purposes of any regulations issued by the Administrator under this Act, matchbooks of conventional size containing not more than 20 paper matches, and which are customarily given away for free with the purchase of smoking articles, shall be considered as adult-written publications which shall be permitted to contain advertising.

(5) AMENDMENT; REVOCATION.—

(A) AUTHORITY.—The Administrator, upon the Administrator's own initiative or upon petition of an interested person, may by a regulation, promulgated in accordance with the requirements of subsection (c) and paragraph (2), amend or revoke a smoking article standard.

(B) EFFECTIVE DATE.—The Administrator may declare a proposed amendment of a smoking article standard to be effective on and after its publication in the Federal Register and until the effective date of any final action taken on such amendment if the Administrator determines that making it so effective is in the public interest.

(6) REFERRAL TO ADVISORY COMMITTEE.—

(A) IN GENERAL.—The Administrator shall refer a proposed regulation for the establishment, amendment, or revocation of a smoking article standard to the Tobacco Products Scientific Advisory Committee for a report and recommendation with respect to any matter involved in the proposed regulation which requires the exercise of scientific judgment.

(B) INITIATION OF REFERRAL.—The Administrator shall make a referral under this paragraph—

(i) on the Administrator's own initiative; or

(ii) upon the request of an interested person that—

(I) demonstrates good cause for the referral; and

(II) is made before the expiration of the period for submission of comments on the proposed regulation.

(C) PROVISION OF DATA.—If a proposed regulation is referred under this paragraph to the Tobacco Products Scientific Advisory Committee, the Administrator shall provide the Advisory Committee with the data and information on which such proposed regulation is based.

(D) REPORT AND RECOMMENDATION.—The Tobacco Products Scientific Advisory Committee shall, within 90 days after the referral of a proposed regulation under this paragraph and after independent study of the data and information furnished to it by the Administrator and other data and information before it, submit to the Administrator a report and recommendation respecting such regulation, together with all underlying data and information and a statement of the reason or basis for the recommendation.

(E) PUBLIC AVAILABILITY.—The Administrator shall make a copy of each report and recommendation under subparagraph (D) publicly available.

SEC. 111. NOTIFICATION AND OTHER REMEDIES.

(a) NOTIFICATION.—If the Administrator determines that—

(1) a tobacco product which is introduced or delivered for introduction into interstate commerce for commercial distribution presents an unreasonable risk of substantial harm materially above the risk for death and disease of tobacco products currently in interstate commerce, to the public health; and

(2) notification under this subsection is necessary to eliminate the unreasonable risk of such harm and no more practicable means is available under the provisions of this Act (other than this section) to eliminate such risk,

the Administrator may issue such order as may be necessary to assure that adequate notification is provided in an appropriate form, by the persons and means best suited under the circumstances involved, to all persons who should properly receive such notification in order to eliminate such risk. The Administrator may order notification by any appropriate means, including public service announcements. Before issuing an order under this subsection, the Administrator shall consult with the persons who are to give notice under the order.

(b) NO EXEMPTION FROM OTHER LIABILITY.—Compliance with an order issued under this section shall not relieve any person from liability under Federal or State law. In awarding damages for economic loss in an action brought for the enforcement of any such liability, the value to the plaintiff in such action of any remedy provided under such order shall be taken into account.

(c) RECALL AUTHORITY.—

(1) IN GENERAL.—If the Administrator finds that there is a reasonable probability that a tobacco product contains a manufacturing or other defect not ordinarily contained in tobacco products on the market that would cause serious, acute adverse health consequences or death, the Administrator shall issue an order requiring the appropriate person (including the manufacturers, importers, distributors, or retailers of the tobacco product) to immediately cease distribution of such tobacco product. The order shall provide the person subject to the order with an opportunity for an informal hearing, to be held not later than 10 days after the date of the issuance of the order, on the actions required by the order and on whether the order should be amended to require a recall of such tobacco product. If, after providing an opportunity for such a hearing, the Administrator determines that inadequate grounds exist to support the actions required by the order, the Administrator shall vacate the order.

(2) AMENDMENT OF ORDER TO REQUIRE RECALL.—

(A) IN GENERAL.—If, after providing an opportunity for an informal hearing under paragraph (1), the Administrator determines that the order should be amended to include a recall of the tobacco product with respect to which the order was issued, the Administrator shall, except as provided in subparagraph (B), amend the order to require a recall. The Administrator shall specify a timetable in which the tobacco product recall will occur and shall require periodic reports to the Administrator describing the progress of the recall.

(B) NOTICE.—An amended order under subparagraph (A)—

(i) shall not include recall of a tobacco product from individuals; and

(ii) shall provide for notice to persons subject to the risks associated with the use of such tobacco product.

In providing the notice required by clause (ii), the Administrator may use the assistance of retailers and other persons who distributed such tobacco product. If a significant number of such persons cannot be identified, the Administrator shall notify such persons under section 705(b).

(3) REMEDY NOT EXCLUSIVE.—The remedy provided by this subsection shall be in addition to remedies provided by subsection (a).

SEC. 112. RECORDS AND REPORTS ON TOBACCO PRODUCTS.

Every person who is a tobacco product manufacturer or importer of a tobacco product shall establish and maintain such records, make such reports, and provide such information, as the Administrator may by regulation reasonably require to assure that such tobacco product is not adulterated or misbranded.

SEC. 113. APPLICATION FOR REVIEW OF CERTAIN SMOKING ARTICLES.

(a) IN GENERAL.—

(1) NEW SMOKING ARTICLE DEFINED.—For purposes of this section the term ''new smoking article'' means—

(A) any smoking article that was not commercially marketed in the United States as of the date of enactment of this Act; and

(B) any smoking article that incorporates a significant modification (including changes in design, component, part, or constituent, including a smoke constituent, or in the content, delivery or form of nicotine, or other additive or ingredient) of a smoking article where the modified product was commercially marketed in the United States after the date of enactment of this Act.

(2) PREMARKET REVIEW REQUIRED.—

(A) NEW PRODUCTS.—An order under subsection (c)(1)(A) for a new smoking article is required unless the product—

(i) is substantially equivalent to a smoking article commercially marketed in the United States as of date of enactment of this Act; and

(ii) is in compliance with the requirements of this Act.

(B) CONSUMER TESTING.—This section shall not apply to smoking articles that are provided to adult tobacco consumers for purposes of consumer testing. For purposes of

this section, the term ''consumer testing'' means an assessment of smoking articles that is conducted by or under the control and direction of a manufacturer for the purpose of evaluating consumer acceptance of such smoking articles, utilizing only the quantity of cigarettes that is reasonably necessary for such assessment

(3) SUBSTANTIALLY EQUIVALENT DEFINED.—

(A) IN GENERAL.—In this section, the term ''substantially equivalent'' or ''substantial equivalence'' means, with respect to the smoking article being compared to the predicate smoking article, that the Administrator by order has found that the smoking article—

(i) has the same general characteristics as the predicate smoking article; or

(ii) has different characteristics and the information submitted contains information, including clinical data if deemed necessary by the Administrator, that demonstrates that it is not appropriate to regulate the product under this section because the product does not raise different questions of public health for the consumer of the product.

(B) CHARACTERISTICS.—In subparagraph (A), the term ''characteristics'' means the materials, ingredients, design, composition, heating source, or other features of a smoking article.

(C) LIMITATION.—A smoking article may not be found to be substantially equivalent to a predicate smoking article that has been removed from the market at the initiative of the Administrator or that has been determined by a judicial order to be misbranded or adulterated.

(4) HEALTH INFORMATION.—As part of a submission respecting a smoking article, the person required to file a premarket notification shall provide an adequate summary of any health information related to the smoking article or state that such information will be made available upon request by any person.

(b) APPLICATION.—

(1) CONTENTS.—An application under this section shall contain—

(A) full reports of all information, published or known to, or which should reasonably be known to, the applicant, concerning investigations which have been made to show the health risks of such smoking article and whether such smoking article presents less risk than other smoking articles;

(B) a full statement of the components, ingredients, additives, and properties, and of the principle or principles of operation, of such smoking article;

(C) a full description of the methods used in, and the facilities and controls used for, the manufacture, processing, and, when relevant, packing and installation of, such smoking article;

(D) an identifying reference to any smoking article standard under section 111 which would be applicable to any aspect of such smoking article, and either adequate information to show that such aspect of such smoking article fully meets such smoking article standard or adequate information to justify any deviation from such standard;

(E) such samples of such smoking article and of components thereof as the Administrator may reasonably require;

(F) specimens of the labeling proposed to be used for such smoking article; and

(G) such other information relevant to the subject matter of the application as the Administrator may require.

(2) REFERRAL TO TOBACCO PRODUCTS SCIENTIFIC ADVISORY COMMITTEE.—Upon receipt of an application meeting the requirements set forth in paragraph (1), the Administrator—

(A) may, on the Administrator's own initiative; or

(B) may, upon the request of an applicant, refer such application to the Tobacco Products Scientific Advisory Committee for reference and for submission (within such period as the Administrator may establish) of a report and recommendation respecting the application, together with all underlying data and the reasons or basis for the recommendation.

(c) ACTION ON APPLICATION.—

(1) DEADLINE.—As promptly as possible, but in no event later than 90 days after the receipt of an application under subsection (b), the Administrator, after considering the report and recommendation submitted under subsection (b)(2), shall—

(A) issue an order that the new product may be introduced or delivered for introduction into interstate commerce if the Administrator finds that none of the grounds specified in paragraph (2) of this subsection applies; or

(B) issue an order that the new product may not be introduced or delivered for introduction into interstate commerce if the Administrator finds (and sets forth the basis for such finding as part of or accompanying such denial) that 1 or more grounds for denial specified in paragraph (2) of this subsection apply.

(2) DENIAL OF APPLICATION.—The Administrator shall deny an application submitted under subsection (b) if, upon the basis of the information submitted to the Administrator as part of the application and any other information before the Administrator with respect to such smoking article, the Administrator finds that—

(A) there is a lack of a showing that permitting such smoking article to be marketed would be appropriate for the protection of the public health;

(B) the methods used in, or the facilities or controls used for, the manufacture, processing, or packing of such smoking article do not conform to the requirements of section 110(e);

(C) based on a fair evaluation of all material facts, the proposed labeling is false or misleading in any particular; or

(D) such smoking article is not shown to conform to a smoking article standard in effect under section 111, and there is a lack of adequate information to justify the deviation from such standard.

(3) DENIAL INFORMATION.—Any denial of an application shall, insofar as the Administrator determines to be practicable, be accompanied by a statement informing the applicant of the measures required to remove such application from deniable form (which measures may include further research by the applicant in accordance with 1 or more protocols prescribed by the Administrator).

(4) BASIS FOR FINDING.—For purposes of this section, the finding as to whether the commercial introduction of a smoking article for which an application has been submitted is appropriate for the protection of the public health shall be determined with respect to the risks and benefits to the users of the smoking article, and taking into account whether such commercial introduction is reasonably likely to increase the morbidly and mortality among individual tobacco users.

(d) WITHDRAWAL AND TEMPORARY SUSPENSION.—

(1) IN GENERAL.—The Administrator shall, upon obtaining, where appropriate, advice on scientific matters from the Tobacco Products Scientific Advisory Committee, and after due notice and opportunity for informal hearing for a smoking article for which an order was issued under subsection (c)(1)(A), issue an order withdrawing the order if the Administrator finds—

(A) that the continued marketing of such smoking article no longer is appropriate for the protection of the public health;

(B) that the application contained or was accompanied by an untrue statement of a material fact;

(C) that the applicant—

(i) has failed to establish a system for maintaining records, or has repeatedly or deliberately failed to maintain records or to make reports, required by an applicable regulation under section 113; or

(ii) has refused to permit access to, or copying or verification of, such records as required by section 110; or

(D) on the basis of new information before the Administrator with respect to such smoking article, evaluated together with the evidence before the Administrator when the application was reviewed, that the methods used in, or the facilities and controls used for, the manufacture, processing, packing, or installation of such smoking article do not conform with the requirements of section 110(e) and were not brought into conformity with such requirements within a reasonable time after receipt of written notice from the Administrator of nonconformity;

(E) on the basis of new information before the Administrator, evaluated together with the evidence before the Administrator when the application was reviewed, that the labeling of such smoking article, based on a fair evaluation of all material facts, is false or misleading in any particular and was not corrected within a reasonable time after receipt of written notice from the Administrator of such fact; or

(F) on the basis of new information before the Administrator, evaluated together with the evidence before the Administrator when such order was issued, that such smoking article is not shown to conform in all respects to a smoking article standard which is in effect under section 111, compliance with which was a condition to the issuance of an order relating to the application, and that there is a lack of adequate information to justify the deviation from such standard.

(2) APPEAL.—The holder of an application subject to an order issued under paragraph (1) withdrawing an order issued pursuant to subsection (c)(1)(A) may, by petition filed on or before the 30th day after the date upon which such holder receives notice of such withdrawal, obtain review thereof in accordance with section 116.

(3) TEMPORARY SUSPENSION.—If, after providing an opportunity for an informal hearing, the Administrator determines there is reasonable probability that the continuation of distribution of a smoking article under an order would cause serious, adverse health consequences or death, that is greater than ordinarily caused by smoking articles on the market, the Administrator shall by order temporarily suspend the authority of the manufacturer to market the product. If the Administrator issues such an order, the Administrator shall proceed expeditiously under paragraph (1) to withdraw such application.

(e) SERVICE OF ORDER.—An order issued by the Administrator under this section shall be served—

(1) in person by any officer or employee of the department designated by the Administrator; or

(2) by mailing the order by registered mail or certified mail addressed to the applicant at the applicant's last known address in the records of the Administrator.

(f) RECORDS.—

(1) ADDITIONAL INFORMATION.—In the case of any smoking article for which an order issued pursuant to subsection (c)(1)(A) for an

application filed under subsection (b) is in effect, the applicant shall establish and maintain such records, and make such reports to the Administrator, as the Administrator may by regulation, or by order with respect to such application, prescribe on the basis of a finding that such records and reports are necessary in order to enable the Administrator to determine, or facilitate a determination of, whether there is or may be grounds for withdrawing or temporarily suspending such order.

(2) ACCESS TO RECORDS.—Each person required under this section to maintain records, and each person in charge of custody thereof, shall, upon request of an officer or employee designated by the Administrator, permit such officer or employee at all reasonable times to have access to and copy and verify such records.

(g) INVESTIGATIONAL SMOKING ARTICLE EXEMPTION FOR INVESTIGATIONAL USE.—The Administrator may exempt smoking articles intended for investigational use from the provisions of this Act under such conditions as the Administrator may by regulation prescribe.

SEC. 114. MODIFIED RISK TOBACCO PRODUCTS.

(a) IN GENERAL.—No person may introduce or deliver for introduction into interstate commerce any modified risk tobacco product unless an order issued pursuant to subsection (g) is effective with respect to such product.

(b) DEFINITIONS.—In this section:

(1) MODIFIED RISK TOBACCO PRODUCT.—The term ''modified risk tobacco product'' means any tobacco product that is sold or distributed for use to reduce harm or the risk of tobacco-related disease associated with commercially marketed tobacco products.

(2) SOLD OR DISTRIBUTED.—

(A) IN GENERAL.—With respect to a tobacco product, the term ''sold or distributed for use to reduce harm or the risk of tobacco-related disease associated with commercially marketed tobacco products'' means a tobacco product—

(i) the label, labeling, or advertising of which represents explicitly or implicitly that—

(I) the tobacco product presents a lower risk of tobacco-related disease or is less harmful than one or more other commercially marketed tobacco products;

(II) the tobacco product or its smoke contains a reduced level of a substance or presents a reduced exposure to a substance; or

(III) the tobacco product or its smoke does not contain or is free of a substance;

(ii) the label, labeling, or advertising of which uses the descriptors ''light'', ''mild'', ''low'', ''medium'', ''ultra light'', ''low tar'' or ''ultra low tar''; or

(iii) the tobacco product manufacturer of which has taken any action directed to consumers through the media or otherwise, other than by means of the tobacco product's label, labeling, or advertising, after the date of enactment of the Act, respecting the product that would be reasonably expected to result in consumers believing that the tobacco product or its smoke may present a lower risk of disease or is less harmful than one or more commercially marketed tobacco products, or presents a reduced exposure to, or does not contain or is free of, a substance or substances.

(B) LIMITATION.—No tobacco product shall be considered to be ''sold or distributed for use to reduce harm or the risk of tobacco-related disease associated with commercially marketed tobacco products'', except as described in subparagraph (A).

(C) SMOKELESS TOBACCO PRODUCT.—No smokeless tobacco product shall be considered to be ''sold or distributed for use to reduce harm or the risk of tobacco-related disease associated with commercially marketed tobacco products''.

(3) EFFECTIVE DATE.—The provisions of paragraph (2)(A)(ii) shall take effect 12 months after the date of enactment of the Act.

(c) TOBACCO DEPENDENCE PRODUCTS.—A product that is intended to be used for the treatment of tobacco dependence, including smoking cessation, is not a modified risk tobacco product under this section if it has been approved as a drug or device by the Center and is subject to the requirements of chapter V.

(d) FILING.—Any person may file with the Administrator an application for a modified risk tobacco product. Such application shall include—

(1) a description of the proposed product and any proposed advertising and labeling;

(2) the conditions for using the product;

(3) the formulation of the product;

(4) sample product labels and labeling;

(5) all documents (including underlying scientific information) relating to research findings conducted, supported, or possessed by the tobacco product manufacturer relating to the effect of the product on tobacco-related diseases and health-related conditions, including information both favorable and unfavorable to the ability of the product to reduce risk or exposure and relating to human health;

(6) data and information on how consumers actually use the tobacco product; and

(7) such other information as the Administrator may require.

(e) PUBLIC AVAILABILITY.—The Administrator shall make the application described in subsection (d) publicly available (except matters in the application which are trade secrets or otherwise confidential, commercial information) and shall request comments by interested persons on the information contained in the application and on the label, labeling, and advertising accompanying such application.

(f) ADVISORY COMMITTEE.—

(1) IN GENERAL.—The Administrator shall refer to the Tobacco Products Scientific Advisory Committee any application submitted under this section.

(2) RECOMMENDATIONS.—Not later than 60 days after the date an application is referred to the Tobacco Products Scientific Advisory Committee under paragraph (1), the Advisory Committee shall report its recommendations on the application to the Administrator.

(g) MARKETING.—

(1) MODIFIED RISK PRODUCTS.—Except as provided in paragraph (2), the Administrator shall, with respect to an application submitted under this section, issue an order that a modified risk product may be commercially marketed only if the Administrator determines that the applicant has demonstrated that such product, as it is actually used by consumers, will—

(A) significantly reduce harm and the risk of tobacco-related disease to individual tobacco users; and

(B) is reasonably likely to result in measurable and substantial reductions in morbidity and mortality among individual tobacco users.

(2) SPECIAL RULE FOR CERTAIN PRODUCTS.—

(A) IN GENERAL.—The Administrator may issue an order that a tobacco product may be introduced or delivered for introduction into interstate commerce, pursuant to an application under this section, with respect to a tobacco product that may not be commercially marketed under paragraph (1) if the Secretary makes the findings required under this paragraph and determines that the applicant has demonstrated that—

(i) such order would be appropriate to promote the public health;

(ii) any aspect of the label, labeling, and advertising for such product that would cause the tobacco product to be a modified risk tobacco product under subsection (b) is limited to an explicit or implicit representation that such tobacco product or its smoke does not contain or is free of a substance or contains a reduced level of a substance, or presents a reduced exposure to a substance in tobacco smoke;

(iii) scientific evidence is not available and, using the best available scientific methods, cannot be made available without conducting long-term epidemiological studies for an application to meet the standards set forth in paragraph (1); and

(iv) the scientific evidence that is available without conducting long-term epidemiological studies demonstrates that a measurable and substantial reduction in morbidity or mortality among individual tobacco users is reasonably likely in subsequent studies.

(B) ADDITIONAL FINDINGS REQUIRED.—To issue an order under subparagraph (A) the Administrator must also find that the applicant has demonstrated that—

(i) the magnitude of the overall reductions in exposure to the substance or substances which are the subject of the application is substantial, such substance or substances are harmful, and the product as actually used exposes consumers to the specified reduced level of the substance or substances;

(ii) the product as actually used by consumers will not expose them to higher levels of other harmful substances compared to the similar types of tobacco products then on the market unless such increases are minimal and the reasonably likely overall impact of use of the product remains a substantial and measurable reduction in overall morbidity and mortality among individual tobacco users;

(iii) testing of actual consumer perception shows that, as the applicant proposes to label and market the product, consumers will not be misled into believing that the product—

(I) is or has been demonstrated to be significantly less harmful; or

(II) presents or has been demonstrated to present significant less of a risk of disease than other commercially marketed tobacco products; and

(iv) issuance of an order with respect to the application is expected to benefit the health of users of tobacco products.

(3) BASIS.—The determinations under paragraphs (1) and (2) shall be based on—

(A) the scientific evidence submitted by the applicant; and

(B) scientific evidence and other information that is made available to the Administrator.

(h) ADDITIONAL CONDITIONS FOR MARKETING.—

(1) MODIFIED RISK PRODUCTS.—The Administrator shall require for the marketing of a product under this section that any advertising or labeling concerning modified risk products enable the public to comprehend the information concerning modified risk and to understand the relative significance of such information in the context of total health and in relation to all of the diseases and health-related conditions associated with the use of tobacco products.

(2) COMPARATIVE CLAIMS.—

(A) IN GENERAL.—The Administrator may require for the marketing of a product under this subsection that a claim comparing a tobacco product to other commercially marketed tobacco products shall compare the tobacco product to a commercially marketed tobacco product that is representative of that type of tobacco product on the market (for example the average value of the top 3

brands of an established regular tobacco product).

(B) QUANTITATIVE COMPARISONS.—The Administrator may also require, for purposes of subparagraph (A), that the percent (or fraction) of change and identity of the reference tobacco product and a quantitative comparison of the amount of the substance claimed to be reduced shall be stated in immediate proximity to the most prominent claim.

(i) POSTMARKET SURVEILLANCE AND STUDIES.—

(1) IN GENERAL.—The Administrator shall require, with respect to a product for which an applicant obtained an order under subsection (g)(1), that the applicant conduct postmarket surveillance and studies for such a tobacco product to determine the impact of the order issuance on consumer perception, behavior, and health, to enable the Administrator to review the accuracy of the determinations upon which the order was based, and to provide information that the Administrator determines is otherwise necessary regarding the use or health risks involving the tobacco product. The results of postmarket surveillance and studies shall be submitted to the Administrator on an annual basis.

(2) SURVEILLANCE PROTOCOL.—Each applicant required to conduct a surveillance of a tobacco product under paragraph (1) shall, within 30 days after receiving notice that the applicant is required to conduct such surveillance, submit, for the approval of the Administrator, a protocol for the required surveillance. The Administrator, within 30 days of the receipt of such protocol, shall determine if the principal investigator proposed to be used in the surveillance has sufficient qualifications and experience to conduct such surveillance and if such protocol will result in collection of the data or other information designated by the Administrator as necessary to protect the public health.

(j) WITHDRAWAL OF AUTHORIZATION.—The Administrator, after an opportunity for an informal hearing, shall withdraw an order under subsection (g) if the Administrator determines that—

(1) the applicant, based on new information, can no longer make the demonstrations required under subsection (g), or the Administrator can no longer make the determinations required under subsection (g);

(2) the application failed to include material information or included any untrue statement of material fact;

(3) any explicit or implicit representation that the product reduces risk or exposure is no longer valid, including if—

(A) a tobacco product standard is established pursuant to section 111;

(B) an action is taken that affects the risks presented by other commercially marketed tobacco products that were compared to the product that is the subject of the application; or

(C) any postmarket surveillance or studies reveal that the order is no longer consistent with the protection of the public health;

(4) the applicant failed to conduct or submit the postmarket surveillance and studies required under subsection (g)(2)(C)(ii) or subsection (i); or

(5) the applicant failed to meet a condition imposed under subsection (h).

(k) CHAPTER IV OR V.—A product for which the Administrator has issued an order pursuant to subsection (g) shall not be subject to chapter IV or V of the Federal Food, Drug, and Cosmetic Act.

(l) IMPLEMENTING REGULATIONS OR GUIDANCE.—

(1) SCIENTIFIC EVIDENCE.—Not later than 2 years after the date of enactment of the Act, the Administrator shall issue regulations or guidance (or any combination thereof) on the scientific evidence required for assessment and ongoing review of modified risk tobacco products. Such regulations or guidance shall—

(A) to the extent that adequate scientific evidence exists, establish minimum standards for scientific studies needed prior to issuing an order under subsection (g) to show a reasonable likelihood that a substantial reduction in morbidity or mortality among individual tobacco users occurs for products described in subsection (g)(1) or is reasonably likely for products described in subsection (g)(2);

(B) include validated biomarkers, intermediate clinical endpoints, and other feasible outcome measures, as appropriate;

(C) establish minimum standards for postmarket studies, that shall include regular and long-term assessments of health outcomes and mortality, intermediate clinical endpoints, consumer perception of harm reduction, and the impact on quitting behavior and new use of tobacco products, as appropriate;

(D) establish minimum standards for required postmarket surveillance, including ongoing assessments of consumer perception; and

(E) establish a reasonable timetable for the Administrator to review an application under this section.

(2) CONSULTATION.—The regulations or guidance issued under paragraph (1) may be developed in consultation with the Institute of Medicine, and with the input of other appropriate scientific and medical experts, on the design and conduct of such studies and surveillance.

(3) REVISION.—The regulations or guidance under paragraph (1) shall be revised on a regular basis as new scientific information becomes available.

(4) NEW TOBACCO PRODUCTS.—Not later than 2 years after the date of enactment of the Act, the Administrator shall issue a regulation or guidance that permits the filing of a single application for any tobacco product that is a new tobacco product under section 114 and which the applicant seeks to commercially market under this section.

SEC. 115. JUDICIAL REVIEW.

(a) RIGHT TO REVIEW.—

(1) IN GENERAL.—Not later than 60 days after—

(A) the promulgation of a regulation under section 111 establishing, amending, or revoking a tobacco product standard; or

(B) a denial of an application under section 114(c),

any person adversely affected by such regulation or denial may file a petition for judicial review of such regulation or denial with the United States Court of Appeals for the District of Columbia or for the circuit in which such person resides or has their principal place of business.

(2) REQUIREMENTS.—

(A) COPY OF PETITION.—A copy of the petition filed under paragraph (1) shall be transmitted by the clerk of the court involved to the Administrator.

(B) RECORD OF PROCEEDINGS.—On receipt of a petition under subparagraph (A), the Administrator shall file in the court in which such petition was filed—

(i) the record of the proceedings on which the regulation or order was based; and

(ii) a statement of the reasons for the issuance of such a regulation or order.

(C) DEFINITION OF RECORD.—In this section, the term ''record'' means—

(i) all notices and other matter published in the Federal Register with respect to the regulation or order reviewed;

(ii) all information submitted to the Administrator with respect to such regulation or order;

(iii) proceedings of any panel or advisory committee with respect to such regulation or order;

(iv) any hearing held with respect to such regulation or order; and

(v) any other information identified by the Administrator, in the administrative proceeding held with respect to such regulation or order, as being relevant to such regulation or order.

(b) STANDARD OF REVIEW.—Upon the filing of the petition under subsection (a) for judicial review of a regulation or order, the court shall have jurisdiction to review the regulation or order in accordance with chapter 7 of title 5, United States Code, and to grant appropriate relief, including interim relief, as provided for in such chapter. A regulation or denial described in subsection (a) shall be reviewed in accordance with section 706(2)(A) of title 5, United States Code.

(c) FINALITY OF JUDGMENT.—The judgment of the court affirming or setting aside, in whole or in part, any regulation or order shall be final, subject to review by the Supreme Court of the United States upon certiorari or certification, as provided in section 1254 of title 28, United States Code.

(d) OTHER REMEDIES.—The remedies provided for in this section shall be in addition to, and not in lieu of, any other remedies provided by law.

(e) REGULATIONS AND ORDERS MUST RECITE BASIS IN RECORD.—To facilitate judicial review, a regulation or order issued under section 110, 111, 112, 113, 114, or 119 shall contain a statement of the reasons for the issuance of such regulation or order in the record of the proceedings held in connection with its issuance.

SEC. 116. JURISDICTION OF AND COORDINATION WITH THE FEDERAL TRADE COMMISSION.

Except where expressly provided in this Act, nothing in this Act shall be construed as limiting or diminishing the authority of the Federal Trade Commission to enforce the laws under its jurisdiction with respect to the advertising, sale, or distribution of tobacco products.

SEC. 117. REGULATION REQUIREMENT.

(a) TESTING, REPORTING, AND DISCLOSURE.—Not later than 36 months after the date of enactment of the Act, the Administrator shall promulgate regulations under this Act that meet the requirements of subsection (b).

(b) CONTENTS OF RULES.—The regulations promulgated under subsection (a)—

(1) shall require annual testing and reporting of tobacco product constituents, ingredients, and additives, including smoke constituents, by brand style that the Administrator determines should be tested to protect the public health, provided that, for purposes of the testing requirements of this paragraph, tobacco products manufactured and sold by a single tobacco product manufacturer that are identical in all respects except the labels, packaging design, logo, trade dress, trademark, brand name, or any combination thereof, shall be considered as a single brand style; and

(2) may require that tobacco product manufacturers, packagers, or importers make disclosures relating to the results of the testing of tar and nicotine through labels or advertising.

(c) AUTHORITY.—The Administrator shall have the authority under this Act to conduct or to require the testing, reporting, or disclosure of tobacco product constituents, including smoke constituents.

(d) JOINT LABORATORY TESTING SERVICES.—The Administrator shall allow any 2 or more tobacco product manufacturers to join together to purchase laboratory testing services required by this section on a group basis

in order to ensure that such manufacturers receive access to, and fair pricing of, such testing services.

(e) EXTENSIONS FOR LIMITED LABORATORY CAPACITY.—

(1) IN GENERAL.—The regulations promulgated under subsection (a) shall provide that a tobacco product manufacturer shall not be considered to be in violation of this section before the applicable deadline, if—

(A) the tobacco products of such manufacturer are in compliance with all other requirements of this Act; and

(B) the conditions described in paragraph (2) are met.

(2) CONDITIONS.—Notwithstanding the requirements of this section, the Administrator may delay the date by which a tobacco product manufacturer must be in compliance with the testing and reporting required by this section until such time as the testing is reported if, not later than 90 days before the deadline for reporting in accordance with this section, a tobacco product manufacturer provides evidence to the Administrator demonstrating that—

(A) the manufacturer has submitted the required products for testing to a laboratory and has done so sufficiently in advance of the deadline to create a reasonable expectation of completion by the deadline;

(B) the products currently are awaiting testing by the laboratory; and

(C) neither that laboratory nor any other laboratory is able to complete testing by the deadline at customary, nonexpedited testing fees.

(3) EXTENSION.—The Administrator, taking into account the laboratory testing capacity that is available to tobacco product manufacturers, shall review and verify the evidence submitted by a tobacco product manufacturer in accordance with paragraph (2). If the Administrator finds that the conditions described in such paragraph are met, the Administrator shall notify the tobacco product manufacturer that the manufacturer shall not be considered to be in violation of the testing and reporting requirements of this section until the testing is reported or until 1 year after the reporting deadline has passed, whichever occurs sooner. If, however, the Administrator has not made a finding before the reporting deadline, the manufacturer shall not be considered to be in violation of such requirements until the Administrator finds that the conditions described in paragraph (2) have not been met, or until 1 year after the reporting deadline, whichever occurs sooner.

(4) ADDITIONAL EXTENSION.—In addition to the time that may be provided under paragraph (3), the Administrator may provide further extensions of time, in increments of no more than 1 year, for required testing and reporting to occur if the Administrator determines, based on evidence properly and timely submitted by a tobacco product manufacturer in accordance with paragraph (2), that a lack of available laboratory capacity prevents the manufacturer from completing the required testing during the period described in paragraph (3).

(f) RULE OF CONSTRUCTION.—Nothing in subsection (d) or (e) shall be construed to authorize the extension of any deadline, or to otherwise affect any timeframe, under any provision of this Act other than this section.

SEC. 118. PRESERVATION OF STATE AND LOCAL AUTHORITY.

(a) IN GENERAL.—

(1) PRESERVATION.—Except as provided in paragraph (2)(A), nothing in this Act, or rules promulgated under this Act, shall be construed to limit the authority of a Federal agency (including the Armed Forces), a State or political subdivision of a State, or the government of an Indian tribe to enact, adopt, promulgate, and enforce any law, rule, regulation, or other measure with respect to tobacco products that is in addition to requirements established under this Act, including a law, rule, regulation, or other measure relating to or prohibiting the sale, distribution, possession, or use of tobacco products by individuals of any age, information reporting to the State. No provision of this Act shall limit or otherwise affect any State, Tribal, or local taxation of tobacco products.

(2) PREEMPTION OF CERTAIN STATE AND LOCAL REQUIREMENTS.—

(A) IN GENERAL.—No State or political subdivision of a State may establish or continue in effect with respect to a tobacco product any requirement which is different from, or in addition to, any requirement under the provisions of this Act relating to tobacco product standards, premarket review, adulteration, misbranding, labeling, registration, good manufacturing standards, or modified risk tobacco products.

(B) EXCEPTION.—Subparagraph (A) does not apply to requirements relating to the sale, distribution, possession, information reporting to the State, use of, tobacco product by individuals of any age. Information disclosed to a State under subparagraph (A) that is exempt from disclosure under section 552(b)(4) of title 5, United States Code, shall be treated as a trade secret and confidential information by the State.

(b) RULE OF CONSTRUCTION REGARDING PRODUCT LIABILITY.—No provision of this Act relating to a tobacco product shall be construed to modify or otherwise affect any action or the liability of any person under the product liability law of any State.

SEC. 119. TOBACCO PRODUCTS SCIENTIFIC ADVISORY COMMITTEE.

(a) ESTABLISHMENT.—Not later than 6 months after the date of enactment of this Act, the Administrator shall establish a 16-member advisory committee, to be known as the Tobacco Products Scientific Advisory Committee (in this section referred to as the ''Advisory Committee'').

(b) MEMBERSHIP.—

(1) IN GENERAL.—

(A) MEMBERS.—The Administrator shall appoint as members of the Tobacco Harm Reduction Advisory Committee individuals who are technically qualified by training and experience in medicine, medical ethics, science, or technology involving the manufacture, evaluation, or use of tobacco products, who are of appropriately diversified professional backgrounds. The committee shall be composed of—

(i) 6 individuals who are physicians, dentists, scientists, or health care professionals practicing in the area of oncology, pulmonology, cardiology, toxicology, pharmacology, addiction, or any other relevant specialty;

(ii) 2 individuals who are an officer or employee of a State or local government or of the Federal Government;

(iii) 2 representatives of the general public;

(iv) 2 representatives of the interests of the tobacco manufacturing industry;

(v) 1 representative of the interests of the small business tobacco manufacturing industry, which position may be filled on a rotating, sequential basis by representatives of different small business tobacco manufacturers based on areas of expertise relevant to the topics being considered by the Advisory Committee;

(vi) 1 individual as a representative of the interests of the tobacco growers; and

(vii) 1 individual who is an expert in illicit trade of tobacco products.

(B) CONFLICTS OF INTEREST.—No members of the committee, other than members appointed pursuant to clauses (iv), (v), and (vi) of subparagraph (A) shall, during the member's tenure on the committee or for the 18-month period prior to becoming such a member, receive any salary, grants, or other payments or support from any business that manufactures, distributes, markets, or sells cigarettes or other tobacco products or government agency with any form of jurisdiction over tobacco products.

(2) LIMITATION.—The Administrator may not appoint to the Advisory Committee any individual who is in the regular full-time employ of the Tobacco Harm Reduction Center or any agency responsible for the enforcement of this Act. The Administrator may appoint Federal officials as ex officio members.

(3) CHAIRPERSON.—The Administrator shall designate 1 of the members appointed under clauses (i), (ii), and (iii) of paragraph (1)(A) to serve as chairperson.

(c) DUTIES.—The Tobacco Products Scientific Advisory Committee shall provide advice, information, and recommendations to the Administrator—

(1) as provided in this Act;

(2) on the implementation of prevention, cessation, and harm reduction policies;

(3) on implementation of policies and programs to fully inform consumers of the respective risks of tobacco products; and

(4) on its review of other safety, dependence, or health issues relating to tobacco products as requested by the Administrator.

(d) COMPENSATION; SUPPORT; FACA.—

(1) COMPENSATION AND TRAVEL.—Members of the Advisory Committee who are not officers or employees of the United States, while attending conferences or meetings of the committee or otherwise engaged in its business, shall be entitled to receive compensation at rates to be fixed by the Administrator, which may not exceed the daily equivalent of the rate in effect under the Senior Executive Schedule under section 5382 of title 5, United States Code, for each day (including travel time) they are so engaged; and while so serving away from their homes or regular places of business each member may be allowed travel expenses, including per diem in lieu of subsistence, as authorized by section 5703 of title 5, United States Code, for persons in the Government service employed intermittently.

(2) ADMINISTRATIVE SUPPORT.—The Administrator shall furnish the Advisory Committee clerical and other assistance.

(3) NONAPPLICATION OF FACA.—Section 14 of the Federal Advisory Committee Act does not apply to the Advisory Committee.

(e) PROCEEDINGS OF ADVISORY PANELS AND COMMITTEES.—The Advisory Committee shall make and maintain a transcript of any proceeding of the panel or committee. Each such panel and committee shall delete from any transcript made under this subsection information which is exempt from disclosure under section 552(b) of title 5, United States Code.

SEC. 120. DRUG PRODUCTS USED TO TREAT TOBACCO DEPENDENCE.

(a) REPORT ON INNOVATIVE PRODUCTS.—

(1) IN GENERAL.—Not later than 3 years after the date of enactment of this Act, the Administrator, after consultation with recognized scientific, medical, and public health experts (including both Federal agencies and nongovernmental entities, the Institute of Medicine of the National Academy of Sciences, and the Society for Research on Nicotine and Tobacco), shall submit to the Congress a report that examines how best to promote, and encourage the development and use by current tobacco users of innovative

tobacco and nicotine products and treatments (including nicotine-based and non-nicotine-based products and treatments) to better achieve, in a manner that best protects and promotes the public health—

(A) total abstinence from tobacco use;

(B) reductions in consumption of tobacco; and

(C) reductions in the harm associated with continued tobacco use by moving current users to noncombustible tobacco products.

(2) RECOMMENDATIONS.—The report under paragraph (1) shall include the recommendations of the Administrator on how the Tobacco Harm and Reduction Center should coordinate and facilitate the exchange of information on such innovative products and treatments among relevant offices and centers within the Center and within the National Institutes of Health, the Centers for Disease Control and Prevention, and other relevant Federal and State agencies.

TITLE II—TOBACCO PRODUCTS WARNINGS; CONSTITUENT AND SMOKE CONSTITUENT DISCLOSURE

SEC. 201. CIGARETTE LABEL AND ADVERTISING WARNINGS.

(a) AMENDMENT.—Section 4 of the Federal Cigarette Labeling and Advertising Act (15 U.S.C. 1333) is amended to read as follows:

"SEC. 4. LABELING.

''(a) LABEL REQUIREMENTS.—

''(1) IN GENERAL.—It shall be unlawful for any person to manufacture, package, sell, offer to sell, distribute, or import for sale or distribution within the United States any cigarettes the package of which fails to bear, in accordance with the requirements of this section, one of the following labels:

''WARNING: Cigarettes are addictive.

''WARNING: Tobacco smoke can harm your children.

''WARNING: Cigarettes cause fatal lung disease.

''WARNING: Cigarettes cause cancer.

''WARNING: Cigarettes cause strokes and heart disease.

''WARNING: Smoking during pregnancy can harm your baby.

''WARNING: Smoking can kill you.

''WARNING: Tobacco smoke causes fatal lung disease in nonsmokers.

''WARNING: Quitting smoking now greatly reduces serious risks to your health.

''(2) PLACEMENT; TYPOGRAPHY; ETC.—Each label statement required by paragraph (1) shall be located in the lower portion of the front panel of the package, directly on the package underneath the cellophane or other clear wrapping. Each label statement shall comprise at least the bottom 25 percent of the front panel of the package. The word 'WARNING' shall appear in capital letters and all text shall be in conspicuous and legible 17-point type, unless the text of the label statement would occupy more than 70 percent of such area, in which case the text may be in a smaller conspicuous and legible type size, provided that at least 60 percent of such area is occupied by required text. The text shall be black on a white background, or white on a black background, in a manner that contrasts, by typography, layout, or color, with all other printed material on the package, in an alternating fashion under the plan submitted under subsection (c).

''(3) DOES NOT APPLY TO FOREIGN DISTRIBUTION.—The provisions of this subsection do not apply to a tobacco product manufacturer or distributor of cigarettes which does not manufacture, package, or import cigarettes for sale or distribution within the United States.

''(4) APPLICABILITY TO RETAILERS.—A retailer of cigarettes shall not be in violation of this subsection for packaging that—

''(A) contains a warning label;

''(B) is supplied to the retailer by a licensee or permit-holding smoking article manufacturer, importer, or distributor; and

''(C) is not altered by the retailer in a way that is material to the requirements of this subsection.

''(b) ADVERTISING REQUIREMENTS.—

''(1) IN GENERAL.—It shall be unlawful for any tobacco product manufacturer, importer, distributor, or retailer of cigarettes to advertise or cause to be advertised within the United States any cigarette unless its advertising bears, in accordance with the requirements of this section, one of the labels specified in subsection (a).

''(2) TYPOGRAPHY, ETC.—Each label statement required by subsection (a) in cigarette advertising shall comply with the standards set forth in this paragraph. For press and poster advertisements, each such statement and (where applicable) any required statement relating to tar, nicotine, or other constituent (including a smoke constituent) yield shall comprise at least 20 percent of the area of the advertisement and shall appear in a conspicuous and prominent format and location at the bottom of each advertisement within the trim area. The word 'WARNING' shall appear in capital letters, and each label statement shall appear in conspicuous and legible type. The text of the label statement shall be black if the background is white and white if the background is black, under the plan submitted under subsection (c). The label statements shall be enclosed by a rectangular border that is the same color as the letters of the statements and that is the width of the first downstroke of the capital 'W' of the word 'WARNING' in the label statements. The text of such label statements shall be in a typeface pro rata to the following requirements: 45-point type for a whole-page broadsheet newspaper advertisement; 39-point type for a half-page broadsheet newspaper advertisement; 39-point type for a whole-page tabloid newspaper advertisement; 27-point type for a half-page tabloid newspaper advertisement; 31.5-point type for a double page spread magazine or whole-page magazine advertisement; 22.5-point type for a 28 centimeter by 3 column advertisement; and 15-point type for a 20 centimeter by 2 column advertisement. The label statements shall be in English, except that—

''(A) in the case of an advertisement that appears in a newspaper, magazine, periodical, or other publication that is not in English, the statements shall appear in the predominant language of the publication; and

''(B) in the case of any other advertisement that is not in English, the statements shall appear in the same language as that principally used in the advertisement.

''(3) MATCHBOOKS.—Notwithstanding paragraph (2), for matchbooks (defined as containing not more than 20 matches) customarily given away with the purchase of smokeless tobacco products, each label statement required by subsection (a) may be printed on the inside cover of the matchbook.

''(c) MARKETING REQUIREMENTS.—

''(1) RANDOM DISPLAY.—The label statements specified in subsection (a)(1) shall be randomly displayed in each 12-month period, in as equal a number of times as is possible on each brand of the product and be randomly distributed in all areas of the United States in which the product is marketed in accordance with a plan submitted by the smokeless tobacco product manufacturer, importer, distributor, or retailer and approved by the Secretary.

''(2) ROTATION.—The label statements specified in subsection (a)(1) shall be rotated quarterly in alternating sequence in advertisements for each brand of cigarettes in accordance with a plan submitted by the smokeless tobacco product manufacturer, importer, distributor, or retailer to, and approved by, the Secretary.

''(3) REVIEW.—The Secretary shall review each plan submitted under paragraph (2) and approve it if the plan—

''(A) will provide for the equal distribution and display on packaging and the rotation required in advertising under this subsection; and

''(B) assures that all of the labels required under this section will be displayed by the smokeless tobacco product manufacturer, importer, distributor, or retailer at the same time.

''(4) APPLICABILITY TO RETAILERS.—This subsection and subsection (b) apply to a retailer only if that retailer is responsible for or directs the label statements required under this section except that this paragraph shall not relieve a retailer of liability if the retailer displays, in a location open to the public, an advertisement that does not contain a warning label or has been altered by the retailer in a way that is material to the requirements of this subsection and subsection (b).''.

(b) EFFECTIVE DATE.—The amendment made by subsection (a) shall take effect 24 months after the date of enactment of this Act. Such effective date shall be with respect to the date of manufacture, provided that, in any case, beginning 30 days after such effective date, a manufacturer shall not introduce into the domestic commerce of the United States any product, irrespective of the date of manufacture, that is not in conformance with section 4 of the Federal Cigarette Labeling and Advertising Act (15 U.S.C. 1333), as amended by subsection (a).

SEC. 202. SMOKELESS TOBACCO LABELS AND ADVERTISING WARNINGS.

(a) AMENDMENT.—Section 3 of the Comprehensive Smokeless Tobacco Health Education Act of 1986 (15 U.S.C. 4402) is amended to read as follows:

"SEC. 3. SMOKELESS TOBACCO WARNING.

''(a) GENERAL RULE.—

''(1) It shall be unlawful for any person to manufacture, package, sell, offer to sell, distribute, or import for sale or distribution within the United States any smokeless tobacco product unless the product package bears, in accordance with the requirements of this Act, one of the following labels:

''WARNING: This product can cause mouth cancer.

''WARNING: This product can cause gum disease and tooth loss.

''WARNING: This product has significantly lower risks for diseases associated with cigarettes.

''WARNING: Smokeless tobacco is addictive.

''(2) The label statements required by paragraph (1) shall be introduced by each smokeless tobacco product manufacturer, packager, importer, distributor, or retailer of smokeless tobacco products concurrently into the distribution chain of such products.

''(3) The provisions of this subsection do not apply to a smokeless tobacco product manufacturer or distributor of any smokeless tobacco product that does not manufacture, package, or import smokeless tobacco products for sale or distribution within the United States.

''(4) A retailer of smokeless tobacco products shall not be in violation of this subsection for packaging that—

''(A) contains a warning label;

''(B) is supplied to the retailer by a licensee or permit-holding smokeless tobacco product manufacturer, importer, or distributor; and

''(C) is not altered by the retailer in a way that is material to the requirements of this subsection.

''(b) REQUIRED LABELS.—

''(1) It shall be unlawful for any smokeless tobacco product manufacturer, packager, importer, distributor, or retailer of smokeless tobacco products to advertise or cause to be advertised within the United States any smokeless tobacco product unless its advertising bears, in accordance with the requirements of this section, one of the labels specified in subsection (a).

''(2)(A) Each label statement required by subsection (a) in smokeless tobacco advertising shall comply with the standards set forth in this paragraph.

''(B) For press and poster advertisements, each such statement and (where applicable) any required statement relating to nicotine, or other constituent yield shall comprise at least 20 percent of the area of the advertisement.

''(C) The word 'WARNING' shall appear in capital letters, and each label statement shall appear in conspicuous and legible type.

''(D) The text of the label statement shall be black on a white background, or white on a black background, in an alternating fashion under the plan submitted under paragraph (3).

''(E) The label statements shall be enclosed by a rectangular border that is the same color as the letters of the statements and that is the width of the first downstroke of the capital 'W' of the word 'WARNING' in the label statements.

''(F) The text of such label statements shall be in a typeface pro rata to the following requirements: 45-point type for a whole-page broadsheet newspaper advertisement; 39-point type for a half-page broadsheet newspaper advertisement; 39-point type for a whole-page tabloid newspaper advertisement; 27-point type for a half-page tabloid newspaper advertisement; 31.5-point type for a double page spread magazine or whole-page magazine advertisement; 22.5-point type for a 28 centimeter by 3 column advertisement; and 15-point type for a 20 centimeter by 2 column advertisement.

''(G) The label statements shall be in English, except that—

''(i) in the case of an advertisement that appears in a newspaper, magazine, periodical, or other publication that is not in English, the statements shall appear in the predominant language of the publication; and

''(ii) in the case of any other advertisement that is not in English, the statements shall appear in the same language as that principally used in the advertisement.

''(3)(A) The label statements specified in subsection (a)(1) shall be randomly displayed in each 12-month period, in as equal a number of times as is possible on each brand of the product and be randomly distributed in all areas of the United States in which the product is marketed in accordance with a plan submitted by the smokeless tobacco product manufacturer, importer, distributor, or retailer and approved by the Secretary.

''(B) The label statements specified in subsection (a)(1) shall be rotated quarterly in alternating sequence in advertisements for each brand of smokeless tobacco product in accordance with a plan submitted by the smokeless tobacco product manufacturer, importer, distributor, or retailer to, and approved by, the Secretary.

''(C) The Secretary shall review each plan submitted under subparagraphs (A) and (B) and approve it if the plan—

''(i) will provide for the equal distribution and display on packaging and the rotation required in advertising under this subsection; and

''(ii) assures that all of the labels required under this section will be displayed by the smokeless tobacco product manufacturer, importer, distributor, or retailer at the same time.

''(D) This paragraph applies to a retailer only if that retailer is responsible for or directs the label statements under this section, unless the retailer displays, in a location open to the public, an advertisement that does not contain a warning label or has been altered by the retailer in a way that is material to the requirements of this subsection.

''(c) TELEVISION AND RADIO ADVERTISING.—It is unlawful to advertise smokeless tobacco on any medium of electronic communications subject to the jurisdiction of the Federal Communications Commission.''.

(b) EFFECTIVE DATE.—The amendment made by subsection (a) shall take effect 24 months after the date of enactment of this Act. Such effective date shall be with respect to the date of manufacture, provided that, in any case, beginning 30 days after such effective date, a manufacturer shall not introduce into the domestic commerce of the United States any product, irrespective of the date of manufacture, that is not in conformance with section 3 of the Comprehensive Smokeless Tobacco Health Education Act of 1986 (15 U.S.C. 4402), as amended by subsection (a).

TITLE III—PUBIC DISCLOSURES BY TOBACCO PRODUCTS MANUFACTURERS

SEC. 301. DISCLOSURES ON PACKAGES OF TOBACCO PRODUCTS.

(a) BACK FACE FOR REQUIRED DISCLOSURES.—For purposes of this section—

(1) the principal face of a package of a tobacco product is the face that has the largest surface area or, for faces with identical surface areas, any of the faces that have the largest surface area; a package shall not be characterized as having more than 2 principal faces;

(2) the front face shall be the principal face of the package;

(3) if the front and back faces are of different sizes in terms of area, then the larger face shall be the front face;

(4) the back face shall be the principal face of a package that is opposite the front face of the package;

(5) the bottom 50 percent of the back face of the package shall be allocated for required package disclosures in accordance with this section; and

(6) if a package of a tobacco product is cylindrical, a contiguous area constituting 30 percent of the total surface area of the cylinder shall be deemed the back face.

(b) REQUIRED INFORMATION ON BACK FACE.—Not later than 24 months after the effective date of this Act, the bottom 50 percent of the back face of a package of a tobacco product shall be available solely for disclosures required by or under this Act, the Federal Cigarette Labeling and Advertising Act, sections 1331–1340 of title 15, United States Code, and any other Federal statute. Such disclosures shall include—

(1) the printed name and address of the manufacturer, packer, or distributor, and any other identification associated with the manufacturer, packer, or distributor or with the tobacco product that the Administrator may require;

(2) a list of ingredients as required by subsection (e); and

(3) the appropriate tax registration number.

(c) PACKAGE DISCLOSURE OF INGREDIENTS.—Not later than 24 months after the effective date of this Act, the package of a tobacco product shall bear a list of the common or usual names of the ingredients present in the tobacco product in an amount greater than 0.1 percent of the total dry weight of the tobacco (including all ingredients), that shall comply with the following:

(1) Such listing of ingredients shall appear under, or be conspicuously accompanied by, the heading ''Tobacco and principal tobacco ingredients''.

(2) Tobacco may be listed as ''tobacco,'' and shall be the first listed ingredient.

(3) After tobacco, the ingredients shall be listed in descending order of predominance, by weight.

(4) Spices and natural and artificial flavors may be listed, respectively, as ''spices'' and ''natural and artificial flavors'' without naming each.

(5) Preservatives may be listed as ''preservatives'' without naming each.

(6) The disclosure of any ingredient in accordance with this section may, at the option of the tobacco product manufacturer, designate the functionality or purpose of that ingredient.

(7) The package say state ''Not for sale to minors''.

(8) In the case of a package of cigarettes, the package shall state that smokeless tobacco has significantly lower risks for disease and death than cigarettes.

SEC. 302. DISCLOSURES ON PACKAGES OF SMOKELESS TOBACCO.

(a) BACK FACE FOR REQUIRED DISCLOSURES.—For purposes of this section—

(1) the principal face of a package of smokeless tobacco is the face that has the largest surface area or, for faces with identical surface areas, any of the faces that have the largest surface area; a package shall not be characterized as having more than two principal faces;

(2) the front or top face shall be the principal face of the package;

(3) if the front or top and back or bottom faces are of different sizes in terms of area, then the larger face shall be the front or top face;

(4) the back or bottom face of the package shall be the principal face of a package that is opposite the front or top face of the package;

(5) beginning 24 months after the effective date of this Act, 50 percent of the back or bottom face of the package shall be allocated for required package disclosures in accordance with this section; and

(6) if the package is cylindrical, a contiguous area constituting 30 percent of the total surface area of the cylinder shall be deemed the back face.

(b) REQUIRED INFORMATION ON BACK OR BOTTOM FACE.—50 percent of the back or bottom face of a package of smokeless tobacco shall be available solely for disclosures required by or under this Act, the Comprehensive Smokeless Tobacco Health Education Act of 1986, sections 4401–4408 of title 15, United States Code, and any other Federal statute. Such disclosures shall include a list of ingredients as required by subsection (e).

(c) PACKAGE DISCLOSURE OF INGREDIENTS.—Commencing 24 months after the effective date of this Act, a package of smokeless tobacco shall bear a list of the common or usual names of the ingredients present in the smokeless tobacco in an amount greater than 0.1 percent of the total dry weight of the tobacco (including all ingredients).

(1) Such listing of ingredients shall appears under, or be conspicuously accompanied by, the heading ''Tobacco and principal tobacco ingredients''.

(2) Tobacco may be listed as ''tobacco,'' and shall be the first listed ingredient.

(3) After tobacco, the ingredients shall be listed in descending order of predominance, by weight.

(4) Spices and natural and artificial flavors may be listed, respectively, as ''spices'' and

''natural and artificial flavors'' without naming each.

(5) Preservatives may be listed as ''preservatives'' without naming each.

(6) The disclosure of any ingredient in accordance with this section may, at the option of the tobacco product manufacturer, designate the functionality or purpose of that ingredient.

(7) Not for sale to minors.

SEC. 303. PUBLIC DISCLOSURE OF INGREDIENTS.

(a) REGULATIONS.—Not later than 24 months after the effective date of this Act, the Administrator shall, by regulation, establish standards under which each tobacco product manufacturer shall disclose publicly, and update at least annually—

(1) a list of the ingredients it uses in each brand style it manufactures for commercial distribution domestically, as provided in subsection (b); and

(2) a composite list of all the ingredients it uses in any of the brand styles it manufactures for commercial distribution domestically, as provided in subsection (c).

(b) INGREDIENTS TO BE DISCLOSED AS TO EACH BRAND STYLE.—

(1) IN GENERAL.—With respect to the public disclosure required by subsection (a)(1), as to each brand style, the tobacco product manufacture shall disclose the common or usual name of each ingredient present in the brand style in an amount greater than 0.1 percent of the total dry weight of the tobacco (including all ingredients).

(2) REQUIREMENTS.—Disclosure under paragraph (1) shall comply with the following:

(A) Tobacco may be listed as ''tobacco,'' and shall be the first listed ingredient.

(B) After tobacco, the ingredients shall be listed in descending order of predominance, by weight.

(C) Spices and natural and artificial flavors may be listed, respectively, as ''spices'' and ''natural and artificial flavors'' without naming each.

(D) Preservatives may be listed as ''preservatives'' without naming each.

(E) The disclosure of any ingredient in accordance with this section may, at the option of the tobacco product manufacturer, designate the functionality or purpose of that ingredient.

(c) AGGREGATE DISCLOSURE OF INGREDIENTS.—

(1) IN GENERAL.—The public disclosure required of a tobacco product manufacturer by subsection (a)(2) shall consist of a single list of all ingredients used in any brand style a tobacco product manufacturer manufactures for commercial distribution domestically, without regard to the quantity used, and including, separately, each spice, each natural or artificial flavoring, and each preservative.

(2) LISTING.—The ingredients shall be listed by their respective common or usual names in descending order of predominance by the total weight used annually by the tobacco product manufacturer in manufacturing tobacco products for commercial distribution domestically.

(d) NO REQUIRED DISCLOSURE OF QUANTITIES.—The Administrator shall not require any public disclosure of quantitative information about any ingredient in a tobacco product.

(e) DISCLOSURE ON WEBSITE.—The public disclosures required by subsection (a) of this section may be by posting on an Internet-accessible website, or other location electronically accessible to the public, which is identified on all packages of a tobacco product manufacturer's tobacco products.

(f) TIMING OF INITIAL REQUIRED DISCLOSURES.—No disclosure pursuant to this section shall be required to commence until the regulations under subsection (a) have been in effect for not less than 1 year.

TITLE IV—PREVENTION OF ILLICIT TRADE IN TOBACCO PRODUCTS

SEC. 401. STUDY AND REPORT ON ILLICIT TRADE.

(a) The Administrator shall, after consultation with other relevant agencies including Customs and Tobacco Tax Bureau, conduct a study of trade in tobacco products that involves passage of tobacco products either between the States or from or to any other country across any border of the United States to—

(1) collect data on such trade in tobacco products, including illicit trade involving tobacco products, and make recommendations on the monitoring and enforcement of such trade;

(2) collect data on any advertising intended to be broadcast, transmitted, or distributed from or to the United States from or to another country and make recommendations on how to prevent or eliminate, and what technologies could help facilitate the elimination of, such advertising; and

(3) collect data on such trade in tobacco products by person that is not—

(A) a participating manufacturer (as that term is defined in section II(jj) of the Master Settlement Agreement of November 23, 1998, between certain of the States and certain tobacco product manufacturers); or

(B) an affiliate or subsidiary of a participating manufacturer.

(b) Not later than 18 months after the effective date of this Act, the Administrator shall submit to the Secretary, and committees of relevant jurisdiction in Congress, a report the recommendations of the study conducted under subsection (a).

SEC. 402. AMENDMENT TO SECTION 1926 OF THE PUBLIC HEALTH SERVICE ACT.

Section 1926 of the Public Health Service Act (42 U.S.C. § 300x–26) is amended by adding at the end thereof the following:

''(e)(1) Subject to paragraphs (2) and (3), for the first fiscal year after enactment and each subsequent fiscal year, the Secretary shall reduce, as provided in subsection (h), the amount of any grant under section 300x–21 of this title for any State that does not have in effect a statute with substantially the following provisions:

''SEC. 1. DISTRIBUTION TO MINORS.

''(a) No person shall distribute a tobacco product to an individual under 18 years of age or a different minimum age established under State law. A person who violates this subsection is liable for a civil money penalty of not less than $25 nor more than $125 for each violation of this subsection;

''(b) The employer of an employee who has violated subsection (a) twice while in the employ of such employer is liable for a civil money penalty of $125 for each subsequent violation by such employee.

''(c) It shall be a defense to a charge brought under subsection (a) that—

''(1) the defendant—

''(A) relied upon proof of age that appeared on its face to be valid in accordance with the Federal Tobacco Act of 2007;

''(B) had complied with the requirements of section 5 and, if applicable, section 7; or

''(C) relied upon a commercially available electronic age verification service to confirm that the person was an age-verified adult; or

''(2) the individual to whom the tobacco product was distributed was at the time of the distribution used in violation of subsection 8(b).

''SEC. 2. PURCHASE, RECEIPT, OR POSSESSION BY MINORS PROHIBITED.

''(a) An individual under 18 years of age or a different minimum age established under State law shall not purchase or attempt to purchase, receive or attempt to receive, possess or attempt to possess, a tobacco product. An individual who violates this subsection is liable for a civil money penalty of not less than $25 nor more than $125 for each such violation, and shall be required to perform not less than four hours nor more than ten hours of community service. Upon the second or each subsequent violation of this subsection, such individual shall be required to perform not less than eight hours nor more than twenty hours of community service.

''(b) A law enforcement agency, upon determining that an individual under 18 years of age or a different minimum age established under State law allegedly purchased, received, possessed, or attempted to purchase, receive, or possess, a tobacco product in violation of subsection (a) shall notify the individual's parent or parents, custodian, or guardian as to the nature of the alleged violation if the name and address of a parent or parents, guardian, or custodian is reasonably ascertainable by the law enforcement agency. The notice required by this subsection shall be made not later than 48 hours after the individual who allegedly violated subsection (a) is cited by such agency for the violation. The notice may be made by any means reasonably calculated to give prompt actual notice, including notice in person, by telephone, or by first-class mail.

''(c) Subsection (a) does not prohibit an individual under 18 years of age or a different minimum age established under State law from possessing a tobacco product during regular working hours and in the course of such individual's employment if the tobacco product is not possessed for such individual's consumption.

''SEC. 3. OUT-OF-PACKAGE DISTRIBUTION.

''It shall be unlawful for any person to distribute cigarettes or a smokeless tobacco product other than in an unopened package that complies in full with section 108 of the Federal Tobacco Act of 2007. A person who distributes a cigarette or a smokeless tobacco product in violation of this section is liable for a civil money penalty of not less than $25 nor more than $125 for each such violation.

''SEC. 4. SIGNAGE.

''It shall be unlawful for any person who sells tobacco products over-the-counter to fail to post conspicuously on the premises where such person sells tobacco products over-the-counter a sign communicating that—

''(1) the sale of tobacco products to individuals under 18 years of age or a different minimum age established under State law is prohibited by law;

''(2) the purchase of tobacco products by individuals under 18 years of age or a different minimum age established under State law is prohibited by law; and

''(3) proof of age may be demanded before tobacco products are sold.

A person who fails to post a sign that complies fully with this section is liable for a civil money penalty of not less than $25 nor more than $125.

''SEC. 5. NOTIFICATION OF EMPLOYEES.

''(a) Within 180 days of the effective date of the Preventing Disease and Death from Tobacco Use Act, every person engaged in the business of selling tobacco products at retail shall implement a program to notify each employee employed by that person who sells tobacco products at retail that—

''(1) the sale or other distribution of tobacco products to any individual under 18 years of age or a different minimum age established under State law, and the purchase, receipt, or possession of tobacco products in a place open to the public by any individual under 18 years of age or a different minimum age established under State law, is prohibited; and

''(2) out-of-package distribution of cigarettes and smokeless tobacco products is prohibited.

Any employer failing to provide the required notice to any employee shall be liable for a civil money penalty of not less than $25 nor more than $125 for each such violation.

''(b) It shall be a defense to a charge that an employer violated subsection (a) of this section that the employee acknowledged receipt, either in writing or by electronic means, prior to the alleged violation, of a statement in substantially the following form:

''I understand that State law prohibits the distribution of tobacco products to individuals under 18 years of age or a different minimum age established under State law and out-of-package distribution of cigarettes and smokeless tobacco products, and permits a defense based on evidence that a prospective purchaser's proof of age was reasonably relied upon and appeared on its face to be valid. I understand that if I sell, give, or voluntarily provide a tobacco product to an individual under 18 years of age or a different minimum age established under State law, I may be found responsible for a civil money penalty of not less than $25 nor more than $125 for each violation. I promise to comply with this law.'''''

''(c) If an employer is charged with a violation of subsection (a) and the employer uses as a defense to such charge the defense provided by subsection (b), the employer shall be deemed to be liable for such violation if such employer pays the penalty imposed on the employee involved in such violation or in any way reimburses the employee for such penalty.

''SEC. 6. SELF-SERVICE DISPLAYS.

''(a) It shall be unlawful for any person who sells tobacco products over-the-counter at retail to maintain packages of such products in any location accessible to customers that is not under the control of a cashier or other employee during regular business hours. This subsection does not apply to any adult-only facility.

''(b) Any person who violates subsection (a) is liable for a civil money penalty of not less than $25 nor more than $125 for each such violation, except that no person shall be responsible for more than one violation per day at any one retail store.

''SEC. 7. DISTRIBUTION BY MAIL OR COURIER.

''(a) It shall be unlawful to distribute or sell tobacco products directly to consumers by mail or courier, unless the person receiving purchase requests for tobacco products takes reasonable action to prevent delivery to individuals who are not adults by—

''(1) requiring that addressees of the tobacco products be age-verified adults;

''(2) making good faith efforts to verify that such addressees have attained the minimum age for purchase of tobacco products established by the respective States wherein the addresses of the addressees are located; and

''(3) addressing the tobacco products delivered by mail or courier to a physical addresses and not to post office boxes.

''(b) Any person who violates subsection (a) is liable for a civil money penalty of not less than $25 nor more than $125 for each such violation.

''SEC. 8. RANDOM UNANNOUNCED INSPECTIONS; REPORTING; AND COMPLIANCE.

''(a) The State Police, or a local law enforcement authority duly designated by the State Police, shall enforce this Act in a manner that can reasonably be expected to reduce the extent to which tobacco products are distributed to individuals under 18 years of age or a different minimum age established under State law and shall conduct random, unannounced inspections in accordance with the procedures set forth in this Act and in regulations issued under section 1926 of the Federal Public Health Service Act (42 U.S.C. § 300x–26).

''(b) The State may engage an individual under 18 years of age or a different minimum age established under State law to test compliance with this Act, except that such an individual may be used to test compliance with this Act only if the testing is conducted under the following conditions:

''(1) Prior to use of any individual under 18 years of age or a different minimum age established under State law in a random, unannounced inspection, written consent shall be obtained from a parent, custodian, or guardian of such individual;

''(2) An individual under 18 years of age or a different minimum age established under State law shall act solely under the supervision and direction of the State Police or a local law enforcement authority duly designated by the State Police during a random, unannounced inspection;

''(3) An individual under 18 years of age or a different minimum age established under State law used in random, unannounced inspections shall not be used in any such inspection at a store in which such individual is a regular customer; and

''(4) If an individual under 18 years of age or a different minimum age established under State law participating in random, unannounced inspections is questioned during such an inspection about such individual's age, such individual shall state his or her actual age and shall present a true and correct proof of age if requested at any time during the inspection to present it.

''(c) Any person who uses any individual under 18 years of age or a different minimum age established under State law, other than as permitted by subsection (b), to test compliance with this Act, is liable for a civil money penalty of not less than $25 nor more than $125 for each such violation.

''(d) Civil money penalties collected for violations of this Act and fees collected under section 9 shall be used only to defray the costs of administration and enforcement of this Act.

''SEC. 9. LICENSURE.

''(a) Each person engaged in the over-the-counter distribution at retail of tobacco products shall hold a license issued under this section. A separate license shall be required for each place of business where tobacco products are distributed at retail. A license issued under this section is not assignable and is valid only for the person in whose name it is issued and for the place of business designated in the license.

''(b) The annual license fee is $25 for each place of business where tobacco products are distributed at retail.

''(c) Every application for a license, including renewal of a license, under this section shall be made upon a form provided by the appropriate State agency or department, and shall set forth the name under which the applicant transacts or intends to transact business, the location of the place of business for which the license is to be issued, the street address to which all notices relevant to the license are to be sent (in this Act referred to as ''notice address''), and any other identifying information that the appropriate State agency or department may require.

''(d) The appropriate State agency or department shall issue or renew a license or deny an application for a license or the renewal of a license within 30 days of receiving a properly completed application and the license fee. The appropriate State agency or department shall provide notice to an applicant of action on an application denying the issuance of a license or refusing to renew a license.

''(e) Every license issued by the appropriate State agency or department pursuant to this section shall be valid for 1 year from the date of issuance and shall be renewed upon application except as otherwise provided in this Act.

''(f) Upon notification of a change of address for a place of business for which a license has been issued, a license shall be reissued for the new address without the filing of a new application.

''(g) The appropriate State agency or department shall notify every person in the State who is engaged in the distribution at retail of tobacco products of the license requirements of this section and of the date by which such person should have obtained a license.

''(h)(1) Except as provided in paragraph (2), any person who engages in the distribution at retail of tobacco products without a license required by this section is liable for a civil money penalty in an amount equal to (i) two times the applicable license fee, and (ii) $50 for each day that such distribution continues without a license.

''(2) Any person who engages in the distribution at retail of tobacco products after a license issued under this section has been suspended or revoked is liable for a civil money penalty of $100 per day for each day on which such distribution continues after the date such person received notice of such suspension or revocation.

''(i) No person shall engage in the distribution at retail of tobacco products on or after 180 days after the date of enactment this Act unless such person is authorized to do so by a license issued pursuant to this section or is an employee or agent of a person that has been issued such a license.

''SEC. 10. SUSPENSION, REVOCATION, DENIAL, AND NONRENEWAL OF LICENSES.

''(a) Upon a finding that a licensee has been determined by a court of competent jurisdiction to have violated this Act during the license term, the State shall notify the licensee in writing, served personally or by registered mail at the notice address, that any subsequent violation of this Act at the same place of business may result in an administrative action to suspend the license for a period determined by the specify the appropriate State agency or department.

''(b) Upon finding that a further violation by this Act has occurred involving the same place of business for which the license was issued and the licensee has been served notice once under subsection (a), the appropriate State agency or department may initiate an administrative action to suspend the license for a period to be determined by the appropriate State agency or department but not to exceed six months. If an administrative action to suspend a license is initiated, the appropriate State agency or department shall immediately notify the licensee in writing at the notice address of the initiation of the action and the reasons therefor and permit the licensee an opportunity, at least 30 days after written notice is served personally or by registered mail upon the licensee, to show why suspension of the license would be unwarranted or unjust.

''(c) The appropriate State agency or department may initiate an administrative action to revoke a license that previously has been suspended under subsection (b) if, after the suspension and during the one-year period for which the license was issued, the licensee committed a further violation of this Act, at the same place of business for which the license was issued. If an administrative action to revoke a license is initiated, the appropriate State agency or department shall immediately notify the licensee in

writing at the notice address of the initiation of the action and the reasons therefor and permit the licensee an opportunity, at least 30 days after written notice is served personally or by registered mail upon the licensee, to show why revocation of the license would be unwarranted or unjust.

''(d) A person whose license has been suspended or revoked with respect to a place of business pursuant to this section shall pay a fee of $50 for the renewal or reissuance of the license at that same place of business, in addition to any applicable annual license fees.

''(e) Revocation of a license under subsection (c) with respect to a place of business shall not be grounds to deny an application by any person for a new license with respect to such place of business for more than 12 months subsequent to the date of such revocation. Revocation or suspension of a license with respect to a particular place of business shall not be grounds to deny an application for a new license, to refuse to renew a license, or to revoke or suspend an existing license at any other place of business.

''(f) A licensee may seek judicial review of an action of the appropriate State agency or department suspending, revoking, denying, or refusing to renew a license under this section by filing a complaint in a court of competent jurisdiction. Any such complaint shall be filed within 30 days after the date on which notice of the action is received by the licensee. The court shall review the evidence de novo.

''(g) The State shall not report any action suspending, revoking, denying, or refusing to renew a license under this section to the Federal Secretary of Health and Human Services, unless the opportunity for judicial review of the action pursuant to subsection (f), if any, has been exhausted or the time for seeking such judicial review has expired.

''SEC. 11. NO PRIVATE RIGHT OF ACTION.

''Nothing in this Act shall be construed to create a right of action by any private person for any violation of any provision of this Act.

''SEC. 12. JURISDICTION AND VENUE.

''Any action alleging a violation of this Act may be brought only in a court of general jurisdiction in the city or county where the violation is alleged to have occurred.

''SEC. 13. REPORT.

''The appropriate State agency or department shall prepare for submission annually to the Federal Secretary of Health and Human Services the report required by section 1926 of the Federal Public Health Service Act (42 U.S.C. 300x–26).''.

''(2) In the case of a State whose legislature does not convene a regular session in fiscal year 2007, and in the case of a State whose legislature does not convene a regular session in fiscal year 2008, the requirement described in subsection (e)(1) as a condition of a receipt of a grant under section 300x–21 of this title shall apply only for fiscal year 2009 and subsequent fiscal years.

''(3) Subsection (e)(1) shall not affect any State or local law that (A) was in effect on the date of introduction of the Federal Tobacco Act of 2007, and (B) covers the same subject matter as the law described in subsection (e)(1). Any State law that meets the conditions of this paragraph shall also be deemed to meet the requirement described in subsection (e)(1) as a condition of a receipt of a grant under section 300x–21 of this title, if such State law is at least as stringent as the law described in subsection (e)(1).

''(f)(1) For the first applicable fiscal year and for each subsequent fiscal year, a funding agreement for a grant under section 300x–21 of this title is a funding agreement under which the State involved will enforce the law described in subsection (e)(1) of this section in a manner that can reasonably be expected to reduce the extent to which tobacco products are available to individuals under the age of 18 or a different minimum age established under State law for the purchase of tobacco products.

''(2) For the first applicable fiscal year and for each subsequent fiscal year, a funding agreement for a grant under section 300x–21 of this title is a funding agreement under which the State involved will—

''(A) conduct random, unannounced inspections to ensure compliance with the law described in subsection (e)(1); and

''(B) annually submit to the Secretary a report describing—

''(i) the activities carried out by the State to enforce such law during the fiscal year preceding the fiscal year for which the State is seeking the grant;

''(ii) the extent of success the State has achieved in reducing the availability of tobacco products to individuals under 18 years of age or a different minimum age established under State law, including the results of the inspections conducted under subparagraph (A); and

''(iii) the strategies to be utilized by the State for enforcing such law during the fiscal year for which the grant is sought.

''(g) The law specified in subsection (e)(1) may be administered and enforced by a State using—

''(1) any amounts made available to the State through a grant under section 300x–21 of this title;

''(2) any amounts made available to the State under section 300w of this title;

''(3) any fees collected for licenses issued pursuant to the law described in subsection (e)(1);

''(4) any fines or penalties assessed for violations of the law specified in subsection (e)(1); or

''(5) any other funding source that the legislature of the State may prescribe by statute.

''(h) Before making a grant under section 300x–21 of this title to a State for the first applicable fiscal year or any subsequent fiscal year, the Secretary shall make a determination of whether the State has maintained compliance with subsections (e) and (f) of this section. If, after notice to the State and an opportunity for a hearing, the Secretary determines that the State is not in compliance with such subsections, the Secretary shall reduce the amount of the allotment under section 300x–21 of this title for the State for the fiscal year involved by an amount equal to—

''(1) In the case of the first applicable fiscal year, 10 percent of the amount determined under section 300x–33 for the State for the fiscal year;

''(2) In the case of the first fiscal year following such applicable fiscal year, 20 percent of the amount determined under section 300x–33 for the State for the fiscal year;

''(3) In the case of the second such fiscal year, 30 percent of the amount determined under section 300x–33 for the State for the fiscal year; and

''(4) In the case of the third such fiscal year or any subsequent fiscal year, 40 percent of the amount determined under section 300x–33 for the State for the fiscal year.

The Secretary shall not have authority or discretion to grant to any State a waiver of the terms and requirements of this subsection or subsection (e) or (f).

''(i) For the purposes of subsections (e) through (h) of this section the term 'first applicable fiscal year' means—

''(1) fiscal year 2009, in the case of any State described in subsection (e)(2) of this section; and

''(2) fiscal year 2008, in the case of any other State.

''(j) For purposes of subsections (e) through (h) of this section, references to section 300x–21 shall include any successor grant programs.''

''(k) As required by paragraph (1), and subject to paragraph (4), an Indian tribe shall satisfy the requirements of subsection (e)(1) of this section by enacting a law or ordinance with substantially the same provisions as the law described in subsection (e)(1).

''(1) An Indian tribe shall comply with subsection (e)(1) of this section within 180 days after the Administrator finds, in accordance with this paragraph, that—

''(A) the Indian tribe has a governing body carrying out substantial governmental powers and duties;

''(B) the functions to be exercised by the Indian tribe under this Act pertain to activities on trust land within the jurisdiction of the tribe; and

''(C) the Indian tribe is reasonably expected to be capable of carrying out the functions required under this section.

Within 2 years of the date of enactment of the Federal Tobacco Act of 2007, as to each Indian tribe in the United States, the Administrator shall make the findings contemplated by this paragraph or determine that such findings cannot be made, in accordance with the procedures specified in paragraph (4).

''(2) As to Indian tribes subject to subsection (e)(1) of this section, the Administrator shall promulgate regulations that—

''(A) provide whether and to what extent, if any, the law described in subsection (e)(1) may be modified as adopted by Indian tribes; and

''(B) ensure, to the extent possible, that each Indian tribe's retailer licensing program under subsection (e)(1) is no less stringent than the program of the State or States in which the Indian tribe is located.

''(3) If with respect to any Indian tribe the Administrator determines that compliance with the requirements of subsection (e)(1) is inappropriate or administratively infeasible, the Administrator shall specify other means for the Indian tribe to achieve the purposes of the law described in subsection (e)(1) with respect to persons who engage in the distribution at retail of tobacco products on tribal lands.

''(4) The findings and regulations promulgated under paragraphs (1) and (2) shall be promulgated in conformance with section 553 of title 5, United States Code, and shall comply with the following provisions:

''(A) In making findings as provided in paragraph (1), and in drafting and promulgating regulations as provided in paragraph (2) (including drafting and promulgating any revised regulations), the Administrator shall confer with, and allow for active participation by, representatives and members of Indian tribes, and tribal organizations.

''(B) In carrying out rulemaking processes under this subsection, the Administrator shall follow the guidance of subchapter III of chapter 5 of title 5, United States Code, commonly known as the 'Negotiated Rulemaking Act of 1990.'

''(C) The tribal participants in the negotiation process referred to in subparagraph (B) shall be nominated by and shall represent the groups described in this subsection and shall include tribal representatives from all geographic regions.

''(D) The negotiations conducted under this paragraph (4) shall be conducted in a timely manner.

''(E) If the Administrator determines that an extension of the deadlines under subsection (k)(1) of this section is appropriate,

the Secretary may submit proposed legislation to Congress for the extension of such deadlines.

''(5) This subsection shall not affect any law or ordinance that (A) was in effect on tribal lands on the date of introduction of the Preventing Disease and Death from Tobacco Use Act, and (B) covers the same subject matter as the law described in subsection (e)(1). Any law or ordinance that meets the conditions of this paragraph shall also be deemed to meet the requirement described in subsection (k)(1), if such law or ordinance is at least as stringent as the law described in subsection (e)(1).

''(6) For purposes of this subsection—

''(A) 'Administrator' means the Administrator of the Tobacco Harm Reduction Center.

''(B) 'Indian tribe' has the meaning assigned that term in section 4(e) of the Indian Self Determination and Education Assistance Act, section 450b(e) of title 25, United States Code.

''(C) 'Tribal lands' means all lands within the exterior boundaries of any Indian reservation, all lands the title to which is held by the United States in trust for an Indian tribe, or lands the title to which is held by an Indian tribe subject to a restriction by the United States against alienation, and all dependent Indian communities.

''(D) 'tribal organization' has the meaning assigned that term in section 4(l) of the Indian Self Determination and Education Assistance Act, section 450b(l) of title 25, United States Code.''.

SEC. 403. ESTABLISHMENT OF RANKINGS.

(a) STANDARDS AND PROCEDURES FOR RANKINGS.—Within 24 months after the effective date of this Act, the Administrator shall, by regulation, after consultation with an Advisory Committee established for such purpose, establish the standards and procedures for promulgating rankings, comprehensible to consumers of tobacco products, of the following categories of tobacco products and also nicotine-containing products on the basis of the relative risks of serious or chronic tobacco-related diseases and adverse health conditions those categories of tobacco products and also nicotine-containing products respectively present—

(1) cigarettes;

(2) loose tobacco for roll-your-own tobacco products;

(3) little cigars;

(4) cigars;

(5) pipe tobacco;

(6) moist snuff;

(7) dry snuff;

(8) chewing tobacco;

(9) other forms of tobacco products, including pelletized tobacco and compressed tobacco, treated collectively as a single category; and

(10) other nicotine-containing products, treated collectively as a single category.

The Administrator shall not have authority or discretion to establish a relative-risk ranking of any category or subcategory of tobacco products or any category or subcategory of nicotine-containing products other than the ten categories specified in this subsection.

(b) CONSIDERATIONS IN PROMULGATING REGULATIONS.—In promulgating regulations under this section, the Administrator—

(1) shall take into account relevant epidemiologic studies and other relevant competent and reliable scientific evidence; and

(2) in assessing the risks of serious or chronic tobacco-related diseases and adverse health conditions presented by a particular category, shall consider the range of tobacco products or nicotine-containing products within the category, and shall give appropriate weight to the market shares of the respective products in the category.

(c) PROMULGATION OF RANKINGS OF CATEGORIES.—Once the initial regulations required by subsection (a) are in effect, the Administrator shall promptly, by order, after notice and an opportunity for comment, promulgate to the general public rankings of the categories of tobacco products and nicotine-containing products in accordance with those regulations. The Administrator shall promulgate the initial rankings of those categories of tobacco products and nicotine-containing products to the general public not later than January 1, 2010. Thereafter, on an annual basis, the Administrator shall, by order, promulgate to the general public updated rankings that are (1) in accordance with those regulations, and (2) reflect the scientific evidence available at the time of promulgation. The Administrator shall open and maintain an ongoing public docket for receipt of data and other information submitted by any person with respect to such annual promulgation of rankings.

TITLE V—ENFORCEMENT PROVISIONS

SEC. 501. PROHIBITED ACTS.

The following acts and the causing thereof are hereby prohibited—

(1) the introduction or delivery for introduction into interstate commerce of any tobacco product that is adulterated or misbranded;

(2) the adulteration or misbranding of any tobacco product in interstate commerce;

(3) the receipt in interstate commerce of any tobacco product that is known to be adulterated or misbranded, and the delivery or proffered delivery thereof for pay or otherwise;

(4) the failure to establish or maintain any record, or make any report or other submission, or to provide any notice required by or under this Act; or the refusal to permit access to, verification of, or copying of any record as required by this Act;

(5) the refusal to permit entry or inspection as authorized by this Act;

(6) the making to the Administrator of a statement, report, certification or other submission required by this Act, with knowledge that such statement, report, certification, or other submission is false in a material aspect;

(7) the manufacturing, shipping, receiving, storing, selling, distributing, possession, or use of any tobacco product with knowledge that it is an illicit tobacco product;

(8) the forging, simulating without proper permission, falsely representing, or without proper authority using any brand name;

(9) the using by any person to his or her own advantage, or revealing, other than to the Administrator or officers or employees of the Agency, or to the courts when relevant in any judicial proceeding under this Act, any information acquired under authority of this Act concerning any item which as a trade secret is entitled to protection; except that the foregoing does not authorize the withholding of information from either House of Congress or from, to the extent of matter within its jurisdiction, any committee or subcommittee of such committee or any joint committee of Congress or any subcommittee of such joint committee;

(10) the alteration, mutilation, destruction, obliteration, or removal of the whole or any part of the labeling of, or the doing of any other act with respect to, a tobacco product, if such act is done while such tobacco product is held for sale (whether or not the first sale) after shipment in interstate commerce, and results in such tobacco product being adulterated or misbranded;

(11) the importation of any tobacco product that is adulterated, misbranded, or otherwise not in compliance with this Act; and

(12) the commission of any act prohibited by section 201 of this Act.

SEC. 502. INJUNCTION PROCEEDINGS.

(a) The district courts of the United States shall have jurisdiction, for cause shown, to restrain violations of this Act, except for violations of section 701(k).

(b) In case of an alleged violation of an injunction or restraining order issued under this section, which also constitutes a violation of this Act, trial shall be by the court, or upon demand of the defendant, by a jury.

SEC. 503. PENALTIES.

(a) CRIMINAL PENALTIES.—Any person who willfully violates a provision of section 501 of this Act shall be imprisoned for not more than one year or fined not more than $25,000, or both.

(b) CIVIL PENALTIES FOR VIOLATION OF SECTION 803.—

(1) Any person who knowingly distributes or sells, other than through retail sale or retail offer for sale, any cigarette brand style in violation of section 803(a)—

(A) for a first offense shall be liable for a civil penalty not to exceed $10,000 for each distribution or sale, or

(B) for a second offense shall be liable for a civil penalty not to exceed $25,000 for each distribution or sale,

except that the penalty imposed against any person with respect to violations during any 30-day period shall not exceed $100,000.

(2) Any retailer who knowingly distributes, sells or offers for sale any cigarette brand style in violation of section 803(a) shall—

(A) for a first offense for each sale or offer for sale of cigarettes, if the total number of packages of cigarettes sold or offered for sale—

(i) does not exceed 50 packages of cigarettes, be liable for a civil penalty not to exceed $500 for each sale or offer for sale, and

(ii) exceeds 50 packages of cigarettes, be liable for a civil penalty not to exceed $1,000 for each sale or offer for sale;

(B) for each subsequent offense for each sale or offer for sale of cigarettes, if the total number of cigarettes sold or offered for sale—

(i) does not exceed 50 packages of cigarettes, be liable for a civil penalty not to exceed $2,000 for each sale or offer for sale, and

(ii) exceeds 50 packages of cigarettes, be liable for a civil penalty not to exceed $5,000 for each sale or offer for sale;

except that the penalty imposed against any person during any 30-day period shall not exceed $25,000.

SEC. 504. SEIZURE.

(a) ARTICLES SUBJECT TO SEIZURE.—

(1) Any tobacco product that is adulterated or misbranded when introduced into or while in interstate commerce or while held for sale (whether or not the first sale) after shipment in interstate commerce, or which may not, under the provisions of this Act, be introduced into interstate commerce, shall be liable to be proceeded against while in interstate commerce, or at any time thereafter, on libel of information and condemned in any district court of the United States within the jurisdiction of which the tobacco product is found. No libel for condemnation shall be instituted under this Act for any alleged misbranding if there is pending in any court a libel for condemnation proceeding under this Act based upon the same alleged misbranding, and not more than one such proceeding shall be instituted if no such proceeding is so pending, except that such limitations shall not apply—

(A) when such misbranding has been the basis of a prior judgment in favor of the United States, in a criminal, injunction, or libel for condemnation proceeding under this Act, or

(B) when the Administrator has probable cause to believe from facts found, without hearing, by the Administrator or any officer or employee of the Agency that the misbranded tobacco product is dangerous to health beyond the inherent danger to health posed by tobacco, or that the labeling of the misbranded tobacco product is fraudulent, or would be in a material respect misleading to the injury or damage of the purchaser or consumer. In any case where the number of libel for condemnation proceedings is limited as above provided, the proceeding pending or instituted shall, on application of the claimant, seasonably made, be removed for trial to any district agreed upon by stipulation between the parties, or, in case of failure to so stipulate within a reasonable time, the claimant may apply to the court of the district in which the seizure has been made, and such court (after giving the United States attorney for such district reasonable notice and opportunity to be heard) shall by order, unless good cause to the contrary is shown, specify a district of reasonable proximity to the claimant's principal place of business, to which the case shall be removed for trial.

(2) The following shall be liable to be proceeded against at any time on libel of information and condemned in any district court of the United States within the jurisdiction of which they are found—

(A) any tobacco product that is an illicit tobacco product;

(B) any container of an illicit tobacco product;

(C) any equipment or thing used in making an illicit tobacco product; and

(D) any adulterated or misbranded tobacco product.

(3)(A) Except as provided in subparagraph (B), no libel for condemnation may be instituted under paragraph (1) or (2) against any tobacco product which—

(i) is misbranded under this Act because of its advertising, and

(ii) is being held for sale to the ultimate consumer in an establishment other than an establishment owned or operated by a manufacturer, packer, or distributor of the tobacco product.

(B) A libel for condemnation may be instituted under paragraph (1) or (2) against a tobacco product described in subparagraph (A) if the tobacco product's advertising which resulted in the tobacco product being misbranded was disseminated in the establishment in which the tobacco product is being held for sale to the ultimate consumer—

(i) such advertising was disseminated by, or under the direction of, the owner or operator of such establishment, or

(ii) all or part of the cost of such advertising was paid by such owner or operator.

(b) PROCEDURES.—The tobacco product, equipment, or other thing proceeded against shall be liable to seizure by process pursuant to the libel, and the procedure in cases under this section shall conform, as nearly as may be, to the procedure in admiralty; except that on demand of either party any issue of fact joined in any such case shall be tried by jury. When libel for condemnation proceedings under this section, involving the same claimant and the same issues of adulteration or misbranding, are pending in two or more jurisdictions, such pending proceedings, upon application of the claimant seasonably made to the court of one such jurisdiction, shall be consolidated for trial by order of such court, and tried in (1) any district selected by the claimant where one of such proceedings is pending; or (2) a district agreed upon by stipulation between the parties. If no order for consolidation is so made within a reasonable time, the claimant may apply to the court of one such jurisdiction and such court (after giving the United States attorney for such district reasonable notice and opportunity to be heard) shall by order, unless good cause to the contrary is shown, specify a district of reasonable proximity to the claimant's principal place of business, in which all such pending proceedings shall be consolidated for trial and tried. Such order of consolidation shall not apply so as to require the removal of any case the date for trial of which has been fixed. The court granting such order shall give prompt notification thereof to the other courts having jurisdiction of the cases covered thereby.

(c) SAMPLES AND ANALYSES.—The court at any time after seizure up to a reasonable time before trial shall by order allow any party to a condemnation proceeding, the party's attorney or agent, to obtain a representative sample of the article seized and a true copy of the analysis, if any, on which the proceeding is based and the identifying marks or numbers, if any, of the packages from which the samples analyzed were obtained.

(d) DISPOSITION OF CONDEMNED TOBACCO PRODUCTS.—(1) Any tobacco product condemned under this section shall, after entry of the decree, be disposed of by destruction or sale as the court may, in accordance with the provisions of this section, direct; and the proceeds thereof, if sold, less the legal costs and charges, shall be paid into the Treasury of the United States; but such tobacco product shall not be sold under such decree contrary to the provisions of this Act or the laws of the jurisdiction in which sold. After entry of the decree and upon the payment of the costs of such proceedings and the execution of a good and sufficient bond conditioned that such article shall not be sold or disposed of contrary to the provisions of this Act or the laws of any State in which sold, the court may by order direct that such tobacco product be delivered to the owner thereof to be destroyed or brought into compliance with the provisions of this Act, under the supervision of an officer or employee duly designated by the Administrator; and the expenses of such supervision shall be paid by the person obtaining release of the tobacco product under bond. If the tobacco product was imported into the United States and the person seeking its release establishes (A) that the adulteration, misbranding, or violation did not occur after the tobacco product was imported, and (B) that the person seeking the release of the tobacco product had no cause for believing that it was adulterated, misbranded, or in violation before it was released from customs custody, the court may permit the tobacco product to be delivered to the owner for exportation under section 709 in lieu of destruction upon a showing by the owner that there is a reasonable certainty that the tobacco product will not be re-imported into the United States.

(2) The provisions of paragraph (1) of this subsection shall, to the extent deemed appropriate by the court, apply to any equipment or other thing which is not otherwise within the scope of such paragraph and which is referred to in paragraph (2) of subsection (a).

(3) Whenever in any proceeding under this section, involving paragraph (2) of subsection (a), the condemnation of any equipment or thing (other than a tobacco product) is decreed, the court shall allow the claim of any claimant, to the extent of such claimant's interest, for remission or mitigation of such forfeiture if such claimant proves to the satisfaction of the court (A) that such claimant has not caused the equipment or thing to be within one of the categories referred to in such paragraph (2) and has no interest in any tobacco product referred to therein, (B) that such claimant has an interest in such equipment or other thing as owner or lienor or otherwise, acquired by such claimant in good faith, and (C) that such claimant at no time had any knowledge or reason to believe that such equipment or other thing was being or would be used in, or to facilitate, the violation of laws of the United States relating to any illicit tobacco product.

(e) COSTS AND FEES.—When a decree of condemnation is entered against the tobacco product or other article, court costs and fees, and storage and other proper expenses shall be awarded against the person, if any, intervening as claimant of the tobacco product or other article.

(f) REMOVAL FOR TRIAL.—In the case of removal for trial of any case as provided by subsection (a) or (b)—

(1) The clerk of the court from which removal is made shall promptly transmit to the court in which the case is to be tried all records in the case necessary in order that such court may exercise jurisdiction.

(2) The court to which such case was removed shall have the powers and be subject to the duties, for purposes of such case, which the court from which removal was made would have had, or to which such court would have been subject, if such case had not been removed.

(g) ADMINISTRATIVE DETENTION OF TOBACCO PRODUCTS.—

(1) DETENTION AUTHORITY.—

(A) IN GENERAL.—An officer or qualified employee of the Agency may order the detention, in accordance with this subsection, of any tobacco product that is found during an inspection, examination, or investigation under this Act conducted by such officer or qualified employee, if the officer or qualified employee has credible evidence or information indicating that such article presents a threat of serious adverse health consequences beyond those normally inherent in the use of tobacco products.

(B) ADMINISTRATOR'S APPROVAL.—A tobacco product or component thereof may be ordered detained under subparagraph (A) if, but only if, the Administrator or an official designated by the Administrator approves the order. An official may not be so designated unless the official is an officer with supervisory responsibility for the inspection, examination, or investigation that led to the order.

(2) PERIOD OF DETENTION.—A tobacco product may be detained under paragraph (1) for a reasonable period, not to exceed 20 days, unless a greater period, not to exceed 30 days, is necessary, to institute an action under subsection (a) or section 702.

(3) SECURITY OF DETAINED TOBACCO PRODUCT.—An order under paragraph (1) may require that the tobacco product to be detained be labeled or marked as detained, and shall require that the tobacco product be maintained in or removed to a secure facility, as appropriate. A tobacco product subject to such an order shall not be transferred by any person from the place at which the tobacco product is ordered detained, or from the place to which the tobacco product is so removed, as the case may be, until released by the Administrator or until the expiration of the detention period applicable under such order, whichever occurs first. This subsection may not be construed as authorizing the delivery of the tobacco product pursuant to the execution of a bond while the tobacco product is subject to the order, and section 709 does not authorize the delivery of the tobacco product pursuant to the execution of a bond while the article is subject to the order.

(4) APPEAL OF DETENTION ORDER.—

(A) IN GENERAL.—With respect to a tobacco product ordered detained under paragraph (1), any person who would be entitled to be a

claimant of such tobacco product if the tobacco product were seized under subsection (a) may appeal the order to the Administrator. Within five days after such an appeal is filed, the Administrator, after providing opportunity for an informal hearing, shall confirm or terminate the order involved, and such confirmation by the Administrator shall be considered a final agency action for purposes of section 702 of title 5, United States Code. If during such five-day period the Administrator fails to provide such an opportunity, or to confirm or terminate such order, the order is deemed to be terminated.

(B) EFFECT OF INSTITUTING COURT ACTION.—The process under subparagraph (A) for the appeal of an order under paragraph (1) terminates if the Administrator institutes an action under subsection (a) or section 702 regarding the tobacco product involved.

SEC. 505. REPORT OF MINOR VIOLATIONS.

Nothing in this Act shall be construed as requiring the Administrator to report for prosecution, or for institution of libel or injunction proceedings, minor violations of this Act whenever the Administrator believes that the public interest will be adequately served by a suitable written notice or warning.

SEC. 506. INSPECTION.

(a) AUTHORITY TO INSPECT.—The Administrator shall have the power to inspect the premises of a tobacco product manufacturer for purposes of determining compliance with this Act, or the regulations promulgated under it. Officers of the Agency designated by the Administrator, upon presenting appropriate credentials and a written notice to the person in charge of the premises, are authorized to enter, at reasonable times, without a search warrant, any factory, warehouse, or other establishment in which tobacco products are manufactured, processed, packaged, or held for domestic distribution. Any such inspection shall be conducted within reasonable limits and in a reasonable manner, and shall be limited to examining only those things, including but not limited to records, relevant to determining whether violations of this Act, or regulations under it, have occurred. No inspection authorized by this section shall extend to financial data, sales data other than shipment data, pricing data, personnel data (other than data as to qualifications of technical and professional personnel performing functions subject to this Act), or research data. A separate notice shall be given for each such inspection, but a notice shall not be required for each entry made during the period covered by the inspection. Each such inspection shall be commenced and completed with reasonable promptness.

(b) REPORT OF OBSERVATIONS.—Before leaving the premises, the officer of the Agency who has supervised or conducted the inspection shall give to the person in charge of the premises a report in writing setting forth any conditions or practices that appear to manifest a violation of this Act, or the regulations under it.

(c) SAMPLES.—If the officer has obtained any sample in the course of inspection, prior to leaving the premises that officer shall give to the person in charge of the premises a receipt describing the samples obtained. As to each sample obtained, the officer shall furnish promptly to the person in charge of the premises a copy of the sample and of any analysis made upon the sample.

SEC. 507. EFFECT OF COMPLIANCE.

Compliance with the provisions of this Act and the regulations promulgated under it shall constitute a complete defense to any civil action, including but not limited to any products liability action, that seeks to recover damages, whether compensatory or punitive, based upon an alleged defect in the labeling or advertising of any tobacco product distributed for sale domestically.

SEC. 508. IMPORTS.

(a) IMPORTS; LIST OF REGISTERED FOREIGN ESTABLISHMENTS; SAMPLES FROM UNREGISTERED FOREIGN ESTABLISHMENTS; EXAMINATION AND REFUSAL OF ADMISSION.—The Secretary of Homeland Security shall deliver to the Administrator, upon request by the Administrator, samples of tobacco products that are being imported or offered for import into the United States, giving notice thereof to the owner or consignee, who may appear before the Administrator and have the right to introduce testimony. The Administrator shall furnish to the Secretary of Homeland Security a list of establishments registered pursuant to subsection (d) of section 109 of this Act, and shall request that, if any tobacco products manufactured, prepared, or processed in an establishment not so registered are imported or offered for import into the United States, samples of such tobacco products be delivered to the Administrator, with notice of such delivery to the owner or consignee, who may appear before the Administrator and have the right to introduce testimony. If it appears from the examination of such samples or otherwise that (1) such tobacco product is forbidden or restricted in sale in the country in which it was produced or from which it was exported, or (2) such tobacco product is adulterated, misbranded, or otherwise in violation of this Act, then such tobacco product shall be refused admission, except as provided in subsection (b) of this section. The Secretary of Homeland Security shall cause the destruction of any such tobacco product refused admission unless such tobacco product is exported, under regulations prescribed by the Secretary of Homeland Security, within ninety days of the date of notice of such refusal or within such additional time as may be permitted pursuant to such regulations.

(b) DISPOSITION OF REFUSED TOBACCO PRODUCTS.—Pending decision as to the admission of a tobacco product being imported or offered for import, the Secretary of Homeland Security may authorize delivery of such tobacco product to the owner or consignee upon the execution by such consignee of a good and sufficient bond providing for the payment of such liquidated damages in the event of default as may be required pursuant to regulations of the Secretary of Homeland Security. If it appears to the Administrator that a tobacco product included within the provisions of clause (3) of subsection (a) of this section can, by relabeling or other action, be brought into compliance with this Act or rendered other than a tobacco product, final determination as to admission of such tobacco product may be deferred and, upon filing of timely written application by the owner or consignee and the execution by such consignee of a bond as provided in the preceding provisions of this subsection, the Administrator may, in accordance with regulations, authorize the applicant to perform such relabeling or other action specified in such authorization (including destruction or export of rejected tobacco products or portions thereof, as may be specified in the Administrator's authorization). All such relabeling or other action pursuant to such authorization shall in accordance with regulations be under the supervision of an officer or employee of the Agency designated by the Administrator, or an officer or employee of the Department of Homeland Security designated by the Secretary of Homeland Security.

(c) CHARGES CONCERNING REFUSED TOBACCO PRODUCTS.—All expenses (including travel, per diem or subsistence, and salaries of officers or employees of the United States) in connection with the destruction provided for in subsection (a) of this section and the supervision of the relabeling or other action authorized under the provisions of subsection (b) of this section, the amount of such expenses to be determined in accordance with regulations, and all expenses in connection with the storage, cartage, or labor with respect to any tobacco product refused admission under subsection (a) of this section, shall be paid by the owner or consignee and, in default of such payment, shall constitute a lien against any future importations made by such owner or consignee.

SEC. 509. TOBACCO PRODUCTS FOR EXPORT.

(a) EXEMPTION FOR TOBACCO PRODUCTS EXPORTED.—Except as provided in subsection (b), a tobacco product intended for export shall be exempt from this Act if—

(1) it is not in conflict with the laws of the country to which it is intended fore export, as shown by either (A) a document issued by the government of that country or (B) a document provided by a person knowledgeable with respect to the relevant laws of that country and qualified by training and experience to opine on whether the tobacco product is or is not in conflict with such laws;

(2) it is labeled on the outside of the shipping package that it is intended for export; and

(3) the particular units of tobacco product intended for export have not been sold or offered for sale in domestic commerce.

(b) PRODUCTS FOR U.S. ARMED FORCES OVERSEAS.—A tobacco product intended for export shall not be exempt from this Act if it is intended for sale or distribution to members or units of the Armed Forces of the United States located outside of the United States.

(c) This Act shall not apply to a person that manufactures and/or distributes tobacco products solely for export under subsection (a), except to the extent such tobacco products are subject to subsection (b).

TITLE VI—MISCELLANEOUS PROVISIONS

SEC. 601. USE OF PAYMENTS UNDER THE MASTER SETTLEMENT AGREEMENT AND INDIVIDUAL STATE SETTLEMENT AGREEMENTS.

(a) REDUCTION OF GRANT AMOUNTS.—(1) For fiscal year 2010 and each subsequent fiscal year, the Secretary shall reduce, as provided in subsection (b), the amount of any grant under section 1921 of the Public Health Service Act (42 U.S.C. § 300x–21) for any State that spends on tobacco control programs from the funds received by such State pursuant to the Master Settlement Agreement, the Florida Settlement Agreement, the Minnesota Settlement Agreement, the Mississippi Memorandum of Understanding, or the Texas Settlement Agreement, as applicable, less than 20 percent of the amounts received by that State from settlement payments.

(2) In the case of a State whose legislature does not convene a regular session in fiscal year 2009 or 2010, and in the case of a State whose legislature does not convene a regular session in fiscal year 2010, the requirement described in subsection (a)(1) as a condition of receipt of a grant under section 1921 of the Public Health Service Act shall apply only for fiscal year 2009 and subsequent fiscal years.

(b) DETERMINATION OF STATE SPENDING.—Before making a grant under section 1921 of the Public Health Service Act, section 300x–21 of title 42, United States Code, to a State for the first applicable fiscal year or any subsequent fiscal year, the Secretary shall make a determination of whether, during the immediately preceding fiscal year, the State has spent on tobacco control programs, from

the funds received by such State pursuant to the Master Settlement Agreement, the Florida Settlement Agreement, the Minnesota Settlement Agreement, the Mississippi Memorandum of Understanding, or the Texas Settlement Agreement, as applicable, at least the amount referenced in (a)(1). If, after notice to the State and an opportunity for a hearing, the Secretary determines that the State has spent less than such amount, the Secretary shall reduce the amount of the allotment under section 300x–21 of title 42, United States Code, for the State for the fiscal year involved by an amount equal to—

(1) in the case of the first applicable fiscal year, 10 percent of the amount determined under section 300x–33 of title 42, United States Code, for the State for the fiscal year;

(2) in the case of the first fiscal year following such applicable fiscal year, 20 percent of the amount determined under section 300x–33 of title 42, United States Code, for the State for the fiscal year;

(3) in the case of the second such fiscal year, 30 percent of the amount determined under section 300x–33 of title 42, United States Code, for the State for the fiscal year; and

(4) in the case of the third such fiscal year or any subsequent fiscal year, 40 percent of the amount determined under section 300x–33 of title 42, United States Code, for the State for the fiscal year.

The Secretary shall not have authority or discretion to grant to any State a waiver of the terms and requirements of this subsection or subsection (a).

(c) DEFINITIONS.—For the purposes of this section—

(1) The term ''first applicable fiscal year'' means—

(A) fiscal year 2011, in the case of any State described in subsection (a)(2) of this section; and

(B) fiscal year 2010, in the case of any other State.

(2) The term ''Florida Settlement Agreement'' means the Settlement Agreement, together with the exhibits thereto, entered into on August 25, 1997, between the State of Florida and signatory tobacco product manufacturers, as specified therein.

(3) The term ''Master Settlement Agreement'' means the Master Settlement Agreement, together with the exhibits thereto, entered into on November 23, 1998, between the signatory States and signatory tobacco product manufacturers, as specified therein.

(4) The term ''Minnesota Settlement Agreement'' means the Settlement Agreement, together with the exhibits thereto, entered into on May 8, 1998, between the State of Minnesota and signatory tobacco product manufacturers, as specified therein.

(5) The term ''Mississippi Memorandum of Understanding'' means the Memorandum of Understanding, together with the exhibits thereto and Settlement Agreement contemplated therein, entered into on July 2, 1997, between the State of Mississippi and signatory tobacco product manufacturers, as specified therein.

(6) The term ''Secretary'' means the Secretary of Health and Human Services.

(7) The term ''Texas Settlement Agreement'' means the Settlement Agreement, together with the exhibits thereto, entered into on January 16, 1998, between the State of Texas and signatory tobacco product manufacturers, as specified therein.

SEC. 602. PREEMPTION OF STATE LAWS IMPLEMENTING FIRE SAFETY STANDARD FOR CIGARETTES.

(a) IN GENERAL.—With respect to fire safety standards for cigarettes, no State or political subdivision shall—

(1) require testing of cigarettes that would be in addition to, or different from, the testing prescribed in subsection (b); or

(2) require a performance standard that is in addition to, or different from, the performance standard set forth in subsection (b).

(b) TEST METHOD AND PERFORMANCE STANDARD.—

(1) To the extent a State or political subdivision enacts or has enacted legislation or a regulation setting a fire safety standard for cigarettes, the test method employed shall be—

(A) the American Society of Testing and Materials (''ASTM'') standard E2187–4, entitled ''Standard Test Method for Measuring the Ignition Strength of Cigarettes'';

(B) for each cigarette on 10 layers of filter paper;

(C) so that a replicate test of 40 cigarettes for each brand style of cigarettes comprises a complete test trial for that brand style; and

(D) in a laboratory that has been accredited in accordance with ISO/IEC 17205 of the International Organization for Standardization (''ISO'') and that has an implemented quality control and quality assurance program that includes a procedure capable of determining the repeatability of the testing results to a repeatability value that is no greater than 0.19.

(2) To the extent a State or political subdivision enacts or has enacted legislation or a regulation setting a fire safety standard for cigarettes, the performance standard employed shall be that no more than 25 percent of the cigarettes of that brand style tested in a complete test in accordance with paragraph (1) exhibit full-length burns

(c) EXCEPTION TO SUBSECTION (b).—In the event that a manufacturer of a cigarette that a State or political subdivision or its respective delegated agency determines cannot be tested in accordance with the test method prescribed in subsection (b)(1)(A), the manufacturer shall propose a test method and performance standard for the cigarette to the State or political subdivision. Upon approval of the proposed test method and a determination by the State or political division that the performance standard proposed by the manufacturer is equivalent to the performance standard prescribed in subsection (b)(2), the manufacturer may employ such test method and performance standard to certify such cigarette pursuant to this subsection notwithstanding subsection (b).

SEC. 603. INSPECTION BY THE ALCOHOL AND TOBACCO TAX TRADE BUREAU OF RECORDS OF CERTAIN CIGARETTE AND SMOKELESS TOBACCO SELLERS.

(a) IN GENERAL.—Any officer of the Bureau of the Alcohol and Tobacco Tax Trade Bureau may, during normal business hours, enter the premises of any person described in subsection (b) for the purposes of inspecting—

(1) any records or information required to be maintained by such person under the provisions of law referred to in subsection (d); or

(2) any cigarettes or smokeless tobacco kept or stored by such person at such premises.

(b) COVERED PERSONS.—Subsection (a) applies to any person who engages in a delivery sale, and who ships, sells, distributes, or receives any quantity in excess of 10,000 cigarettes, or any quantity in excess of 500 single-unit consumer-sized cans or packages of smokeless tobacco, within a single month.

(c) RELIEF.—

(1) IN GENERAL.—The district courts of the United States shall have the authority in a civil action under this subsection to compel inspections authorized by subsection (a).

(2) VIOLATIONS.—Whoever violates subsection (a) or an order issued pursuant to paragraph (1) shall be subject to a civil penalty in an amount not to exceed $10,000 for each violation.

(d) COVERED PROVISIONS OF LAW.—The provisions of law referred to in this subsection are—

(1) the Act of October 19, 1949 (15 U.S.C. 375; commonly referred to as the ''Jenkins Act'');

(2) chapter 114 of title 18, United States Code; and

(3) this Act.

(e) DELIVERY SALE DEFINED.—In this section, the term ''delivery sale'' has the meaning given that term in 2343(e) of title 18, United States Code, as amended by this Act.

SEC. 604. SEVERABILITY.

If any provision of this Act, the amendments made by this Act, or the application of any provision of this Act to any person or circumstance is held to be invalid, the remainder of this Act, the amendments made by this Act, and the application of the provisions of this Act to any other person or circumstance shall not be affected, and shall continue to be enforced to the fullest extent possible.

TITLE VII—TOBACCO GROWER PROTECTION

SEC. 701. TOBACCO GROWER PROTECTION.

No provision in this Act shall allow the Administrator or any other person to require changes to traditional farming practices, including standard cultivation practices, curing processes, seed composition, tobacco type, fertilization, soil, record keeping, or any other requirement affecting farming practices.

TITLE VIII—RESTRICTIONS ON YOUTH ACCESS TO TOBACCO PRODUCTS AND EXPOSURE OF YOUTHS TO TOBACCO PRODUCT MARKETING AND ADVERTISING

SEC. 801. PROHIBITIONS ON YOUTH TARGETING.

Effective beginning on the date that is 18 months after the effective date of this Act, no person shall engage in any of the following activities or practices in the advertising, promotion, or marketing of any tobacco product:

(1) The use, or causing the use, of any cartoon in the advertising, promoting, packaging, or labeling of any tobacco product.

(2) The use, or causing the use, of any human image in the advertising, promoting, packaging, or labeling of any tobacco product, except for the following:

(A) The use, or continued use, in advertising, promoting, marketing, packaging, or labeling of any human image appearing on a tobacco product package before December 31, 2009.

(B) The use, or continued use, of a human image in the advertising, promoting, or marketing of a tobacco product, if conducted solely in an adult-only facility or facilities.

(C) The use, or continued use, of a human image in a tobacco product communication means directed solely to persons that the tobacco product manufacturer has a good-faith belief are age-verified adults.

(3) The advertising of tobacco products in any magazine or newspaper intended for distribution to the general public.

(4) The engaging in any brand name sponsorship in the United States, other than a brand name sponsorship occurring solely in an adult-only facility or facilities.

(5) The engaging in any brand name sponsorship of any event in the United States in which any paid participants or contestants are youths.

(6) The sponsoring of any athletic event between opposing teams in any football, basketball, baseball, soccer, or hockey league.

(7)(A) The securing of a right, by agreement, to name any stadium or arena located within the United States with a brand name; or

(B) otherwise causing a stadium or arena located within the United States to be named with a brand name.

(8) The securing of a right by agreement pursuant to which payment is made or other consideration is provided to use a brand name in association with any football, basketball, baseball, soccer, or hockey league, or any team involved in any such league.

(9) The use of, or causing the use of, by agreement requiring the payment of money or other consideration, a brand name with any nationally recognized or nationally established trade name or brand designation of any non-tobacco item or service, or any nationally recognized or nationally established sports team, entertainment group or individual celebrity for purposes of advertising, except for an agreement between or among persons that enter into such agreement for the sole purpose of avoiding infringement claims.

(10) The license, express authorization, or otherwise causing of any person to use or advertise within the United States any brand name in a manner that—

(A) does not pertain to a tobacco product; or

(B) causes that person to use the brand name to advertise, promote, package or label, distribute, or sell any product or service that is not a tobacco product.

(11) The marketing, distribution, offering, selling, licensing, or authorizing of, or the causing to be marketed, distributed, offered, sold, licensed, or authorized, any apparel or other merchandise (other than a tobacco product) bearing a brand name, except—

(A) apparel or other merchandise that is used by individuals representing a tobacco product manufacturer within an adult-only facility and that is not distributed, by sale or otherwise, to any member of the general public;

(B) apparel or merchandise provided to an adult employee of a tobacco product manufacturer for use by such employee;

(C) items or materials used to hold or display tobacco products at retail;

(D) items or materials the sole function of which is to advertise tobacco products;

(E) written or electronic publications;

(F) coupons or other items used by adults solely in connection with the purchase of tobacco products;

(G) that the composition, structure, form, or appearance of any tobacco product, package, label, or labeling shall not be affected by the prohibitions of this paragraph; and

(H) that no person shall be required to retrieve, collect or otherwise recover any item or material that was marketed, distributed, offered, sold, licensed, or caused to be marketed, distributed, offered, sold, or licensed by such person.

(12) The distribution, or causing the distribution, of any free sample domestically, except in an adult-only facility or facilities to individuals who are age-verified adults.

(13) The making of, or causing to be made, any payment or the payment of, or causing to be paid, any other consideration to any other person to use, display, make reference to, or use as a prop in any performance medium (for the purposes of this paragraph, the terms ''performance medium'' and ''performance media'' mean any motion picture, television show, theatrical production or other live performance, live or recorded performance of music, commercial film or video, or video game), any tobacco product, tobacco product package, advertisement for a tobacco product, or any other item bearing a brand name; except for the following:

(A) Performance media for which the audience or viewers are within one or more adult-only facilities, if such performance media are not audible or visible to persons outside such adult-only facility or facilities.

(B) Performance media not intended to be heard or viewed by the general public.

(A) Instructional performance media that concern tobacco products and their use, and that are intended to be heard or viewed only by, or provided only to, age-verified adults.

(A) Performance media used in tobacco product communications to age-verified adults.

(14) Engaging in outdoor advertising or transit advertisements of tobacco products within the United States, except for the following:

(A) Advertising that is within an adult-only facility.

(B) The use of outdoor advertising for purposes of identification of an adult-only facility, to the extent that such outdoor advertising is placed at the site, premises, or location of the adult-only facility.

(C) The use of outdoor advertising in identifying a brand name sponsorship at an adult-only facility, if such outdoor advertising—

(i) is placed at the site, premises, or location of the adult-only facility where such brand name sponsorship will occur no more than 30 days before the start of the initial sponsored event; and

(ii) is removed within 10 days after the end of the last sponsored event.

(15) The distribution or sale domestically of any package or other container of cigarettes containing fewer than 20 cigarettes.

(16) The advertising of tobacco products on any broadcast, cable, or satellite transmission to a television or radio receiver, or other medium of electronic communication subject to the jurisdiction of the Federal Communications Commission, except electronic communications—

(A) contained on log-in or home pages containing no tobacco product advertising other than brand name identification;

(B) in an adult-only facility or facilities; or

(C) through the Internet or other individual user-accessible electronic communication means, including websites accessible using the Internet, if the advertiser takes reasonable action to restrict access to individuals who are adults by—

(i) requiring individuals accessing such electronic communications to be age-verified adults, and

(ii) making good faith efforts to verify that such individuals are adults.

(18) The distribution or sale of tobacco products directly to consumers by mail or courier, unless the person receiving purchase requests for tobacco products takes reasonable action to prevent delivery to individuals who are not adults by—

(A) requiring that the addressees of the tobacco products be age-verified adults;

(B) making good faith efforts to verify that such addressees are adults; and

(C) addressing the tobacco products delivered by mail, courier or common carrier to a physical address and not a post office box.

(19) The providing of any gift of a non-tobacco product, except matches, in connection with the purchase of a tobacco product.

(20) The engaging in the sponsorship or promotion, or causing the sponsorship or promotion, of any consumer sweepstakes, contest, drawing, or similar activity resulting in the award of a prize in connection with advertising.

(21) The offering, promoting, conducting, or authorizing, or causing to be offered, promoted, conducted, or authorized, any consumer sweepstakes, drawing, contest, or other activity resulting in the award of a prize, based on redemption of a proof-of-purchase, coupon, or other item awarded as a result of the purchase or use of a tobacco product.

(22) The making of, or causing to be made, any payment or the payment of, or causing to be paid, any other consideration, to any other person with regard to the display or placement of any cigarettes, or any advertising for cigarettes, in any retail establishment that is not an adult-only facility.

TITLE IX—USER FEES

SEC. 901. USER FEES.

(a) ASSESSMENT OF USER FEES.—The Administrator shall assess an annual user fee for each fiscal year beginning in fiscal year 2010, in an amount calculated in accordance with this section, upon each tobacco product manufacturer (including each importer) that is subject to this Act.

(b) USE OF FEE.—The Administrator shall utilize an amount equal to the amount of user fees collected under this section in each fiscal year to pay for the costs of the activities of the Tobacco Regulatory Agency related to the regulation of tobacco products under this Act.

(c) AMOUNT OF FEE.—

(1) IN GENERAL.—Except as provided in paragraph (2), the total amount of user fees assessed for each fiscal year pursuant to this section shall be sufficient, and shall not exceed the amount necessary, to pay for the costs of the activities described in subsection (b) for that fiscal year.

(2) TOTAL.—The total assessment under this section—

(A) for fiscal year 2010 shall be $100,000,000; and

(B) for each subsequent fiscal year, shall not exceed the limit on the assessment imposed during the previous fiscal year, as adjusted by the Administrator (after notice, published in the Federal Register) to reflect the greater of—

(i) the total percentage change that occurred in the Consumer Price Index for all urban consumers (all items; United States city average) for the 12-month period ending on June 30 preceding the fiscal year for which fees are being established; or

(ii) the total percentage change for the previous fiscal year in basic pay under the General Schedule in accordance with section 5332 of title 5, United States Code, as adjusted by any locality-based comparability payment pursuant to section 5304 of such title for Federal employees stationed in the District of Columbia.

(3) NOTIFICATION.—The Administrator shall notify each tobacco product manufacturer subject to this section of the amount of the annual assessment imposed on such tobacco product manufacturer under subsection (d). Such notifications shall occur not later than the July 31 prior to the beginning of the fiscal year for which such assessment is made, and payments of all assessments shall be made not later than 60 days after each such notification. Such notification shall contain a complete list of the assessments imposed on tobacco product manufacturers for that fiscal year.

(d) LIABILITY OF TOBACCO PRODUCT MANUFACTURERS FOR USER FEES.—

(1) IN GENERAL.—The user fee to be paid by each tobacco product manufacturer shall be determined in each fiscal year by multiplying—

(A) such tobacco product manufacturer's market share of tobacco products, as determined under regulations issued pursuant to subsection (e); by

(B) the total user fee assessment for such fiscal year, as determined under subsection (c).

(2) LIMITATION.—Except as provided in paragraph (3), no tobacco product manufacturer shall be required to pay a percentage of a total annual user fee for all tobacco product manufacturers that exceeds the market share of such manufacturer.

(3) FAILURE TO PAY.—If—

(A) a tobacco product manufacturer fails to pay its user fee share in full by the due date;

(B) the Administrator, after diligent inquiry, concludes that such manufacturer is unlikely to pay its user fee share in full by the time such payment will be needed by the Administrator; and

(C) the Administrator and the Department of Justice make diligent efforts to obtain payment in full from such tobacco product manufacturer;

the Administrator may re-allocate the unpaid amount owed by that tobacco product manufacturer to the other tobacco product manufacturers on the basis of their respective market shares. If the Administrator takes such action, the Administrator shall set a reasonable time, not less than 60 days from the date of the notice of the amount due, for payment of that amount. If and to the extent that the Administrator ultimately receives from that tobacco product manufacturer or any successor to such tobacco product manufacturer any payment in respect of the previously unpaid obligation, the Administrator shall credit such payment to the tobacco product manufacturers that paid portions of the re-allocated amount, in proportion to their respective payments of such amount.

(e) REGULATIONS.—Not later than 12 months after the date of enactment of this Act, the Administrator shall, by regulation, establish a system for determining the market shares of tobacco products for each tobacco product manufacturer subject to this section. In promulgating regulations under this subsection, the Administrator shall—

(1) take into account the differences between categories and subcategories of tobacco products in terms of sales, manner of unit packaging, and any other factors relevant to the calculation of market share for a tobacco product manufacturer;

(2) take into account that different tobacco product manufacturers rely to varying degrees on the sales of different categories and subcategories of tobacco products; and

(3) provide that the market share of tobacco products for each tobacco product manufacturer shall be recalculated on an annual basis.

SA 1245. Ms. STABENOW (for herself and Ms. MURKOWSKI) submitted an amendment intended to be proposed by her to the bill H.R. 1256, to protect the public health by providing the Food and Drug Administration with certain authority to regulate tobacco products, to amend title 5, United States Code, to make certain modifications in the Thrift Savings Plan, the Civil Service Retirement System, and the Federal Employees' Retirement System, and for other purposes; which was ordered to lie on the table; as follows:

At the appropriate place, insert the following:

SEC. _. REPORTING OF DATA IN APPLICATIONS FOR DRUGS, BIOLOGICAL PRODUCTS, AND DEVICES.

(a) DRUGS.—

(1) NEW DRUG APPLICATIONS.—Section 505(b) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(b)) is amended—

(A) in paragraph (1), in the second sentence—

(i) by striking ''drug, and (G)'' and inserting ''drug; (G)''; and

(ii) by inserting before the period the following: ''; and (H) the information required under paragraph (7)''; and

(B) by adding at the end the following:

''(7)(A) With respect to clinical data in an application under this subsection, the Secretary may deny such an application if the application fails to meet the requirements of sections 314.50(d)(5)(v) and 314.50(d)(5)(vi)(a) of title 21, Code of Federal Regulations.

''(B) The Secretary shall modify the sections referred to in subparagraph (A) to require that an application under this subsection include any clinical data possessed by the applicant that relates to the safety or effectiveness of the drug involved by gender, age, and racial subgroup.

''(C) Promptly after approving an application under this subsection, the Secretary shall, through an Internet site of the Department of Health and Human Services, make available to the public the information submitted to the Secretary pursuant to subparagraphs (A) and (B), subject to sections 301(j) and 520(h)(1) of this Act, subsection (b)(4) of section 552 of title 5, United States Code (commonly referred to as the 'Freedom of Information Act'), and other provisions of law that relate to trade secrets or confidential commercial information.

''(D) The Secretary shall develop guidance for staff of the Food and Drug Administration to ensure that applications under this subsection are adequately reviewed to determine whether the applications include the information required pursuant to subparagraphs (A) and (B).''.

(2) INVESTIGATIONAL NEW DRUG APPLICATIONS.—Section 505(i) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(i)) is amended—

(A) in paragraph (2), by striking ''Subject to paragraph (3),'' and inserting ''Subject to paragraphs (3) and (5),'' ; and

(B) by adding at the end the following:

''(5)(A) The Secretary may place a clinical hold (as described in paragraph (3)) on an investigation if the sponsor of the investigation fails to meet the requirements of section 312.33(a) of title 21, Code of Federal Regulations.

''(B) The Secretary shall modify the section referred to in subparagraph (A) to require that reports under such section include any clinical data possessed by the sponsor of the investigation that relates to the safety or effectiveness of the drug involved by gender, age, and racial subgroup.''.

(b) BIOLOGICAL PRODUCT LICENSE APPLICATIONS.—Section 351 of the Public Health Service Act (42 U.S.C. 262) is amended by adding at the end the following:

''(k) The provisions of section 505(b)(7) of the Federal Food, Drug, and Cosmetic Act (relating to clinical data submission) apply with respect to an application under subsection (a) of this section to the same extent and in the same manner as such provisions apply with respect to an application under section 505(b) of such Act.''.

(c) DEVICES.—

(1) PREMARKET APPROVAL.—Section 515 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360e) is amended—

(A) in subsection (c)(1)—

(i) in subparagraph (G)—

(I) by moving the margin 2 ems to the left; and

(II) by striking ''and'' after the semicolon at the end;

(ii) by redesignating subparagraph (H) as subparagraph (I); and

(iii) by inserting after subparagraph (G) the following subparagraph:

''(H) the information required under subsection (d)(7); and''; and

(B) in subsection (d), by adding at the end the following paragraph:

''(7) To the extent consistent with the regulation of devices, the provisions of section 505(b)(7) (relating to clinical data submission) apply with respect to an application for premarket approval of a device under subsection (c) of this section to the same extent and in the same manner as such provisions apply with respect to an application for premarket approval of a drug under section 505(b).''.

(2) INVESTIGATIONAL DEVICES.—Section 520(g)(2) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360j(g)(2)) is amended by adding at the end the following subparagraph:

''(D) To the extent consistent with the regulation of devices, the provisions of section 505(i)(5) (relating to individual study information) apply with respect to an application for an exemption pursuant to subparagraph (A) of this paragraph to the same extent and in the same manner as such provisions apply with respect to an application for an exemption under section 505(i).''.

(d) RULES OF CONSTRUCTION.—This Act and the amendments made by this Act may not be construed—

(1) as establishing new requirements under the Federal Food, Drug, and Cosmetic Act relating to the design of clinical investigations that were not otherwise in effect on the day before the date of the enactment of this Act; or

(2) as having any effect on the authority of the Secretary of Health and Human Services to enforce regulations under the Federal Food, Drug, and Cosmetic Act that are not expressly referenced in this Act or the amendments made by this Act.

(e) APPLICATION.—This section and the amendments made by this section apply only with respect to applications received under section 505 or 515 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355, 360e) or section 351 of the Public Health Service Act (42 U.S.C. 262) on or after the date of the enactment of this Act.

SA 1246. Mr. BURR (for himself and Mrs. HAGAN) submitted an amendment intended to be proposed to amendment SA 1247 proposed by Mr. DODD to the bill H.R. 1256, to protect the public health by providing the Food and Drug Administration with certain authority to regulate tobacco products, to amend title 5, United States Code, to make certain modifications in the Thrift Savings Plan, the Civil Service Retirement System, and the Federal Employees' Retirement System, and for other purposes; as follows:

Strike all after the enacting clause and insert the following:

SECTION 1. SHORT TITLE; TABLE OF CONTENTS.

(a) SHORT TITLE.—This Act may be cited as the ''Preventing Disease and Death from Tobacco Use Act''.

(b) TABLE OF CONTENTS.—The table of contents of this Act is as follows:

SEC. 2. FINDINGS.

The Congress finds the following:

(1) Cigarette smoking is a leading cause of preventable deaths in the United States. Cigarette smoking significantly increases the risk of developing lung cancer, heart disease, chronic bronchitis, emphysema and other serious diseases with adverse health conditions.

(2) The risk for serious diseases is significantly affected by the type of tobacco product and the frequency, duration and manner of use.

(3) No tobacco product has been shown to be safe and without risks. The health risks associated with cigarettes are significantly greater than those associated with the use of smoke-free tobacco and nicotine products.

(4) Nicotine in tobacco products is addictive but is not considered a significant threat to health.

(5) It is the smoke inhaled from burning tobacco which poses the most significant risk of serious diseases.

(6) Quitting cigarette smoking significantly reduces the risk for serious diseases.

(7) Adult tobacco consumers have a right to be fully and accurately informed about the risks of serious diseases, the significant differences in the comparative risks of different tobacco and nicotine-based products, and the benefits of quitting. This information should be based on sound science.

(8) Governments, public health officials, tobacco manufacturers and others share a responsibility to provide adult tobacco consumers with accurate information about the various health risks and comparative risks associated with the use of different tobacco and nicotine products.

(9) Tobacco products should be regulated in a manner that is designed to achieve significant and measurable reductions in the morbidity and mortality associated with tobacco use. Regulations should enhance the information available to adult consumers to permit them to make informed choices, and encourage the development of tobacco and nicotine products with lower risks than cigarettes currently sold in the United States.

(10) The form of regulation should be based on the risks and comparative risks of tobacco and nicotine products and their respective product categories.

(11) The regulation of marketing of tobacco products should be consistent with constitutional protections and enhance an adult consumer's ability to make an informed choice by providing accurate information on the risks and comparative risks of tobacco products.

(12) Reducing the diseases and deaths associated with the use of cigarettes serves public health goals and is in the best interest of consumers and society. Harm reduction should be the critical element of any comprehensive public policy surrounding the health consequences of tobacco use.

(13) Significant reductions in the harm associated with the use of cigarettes can be achieved by providing accurate information regarding the comparative risks of tobacco products to adult tobacco consumers, thereby encouraging smokers to migrate to the use of smoke-free tobacco and nicotine products, and by developing new smoke-free tobacco and nicotine products and other actions.

(14) Governments, public health officials, manufacturers, tobacco producers and consumers should support the development, production, and commercial introduction of tobacco leaf, and tobacco and nicotine-based products that are scientifically shown to reduce the risks associated with the use of existing tobacco products, particularly cigarettes.

(15) Adult tobacco consumers should have access to a range of commercially viable tobacco and nicotine-based products.

(16) There is substantial scientific evidence that selected smokeless tobacco products can satisfy the nicotine addiction of inveterate smokers while eliminating most, if not all, risk of pulmonary and cardiovascular complications of smoking and while reducing the risk of cancer by more than 95 percent.

(17) Transitioning smokers to selected smokeless tobacco products will eliminate environmental tobacco smoke and fire-related hazards.

(18) Current ''abstain, quit, or die'' tobacco control policies in the United States may have reached their maximum possible public health benefit because of the large number of cigarette smokers either unwilling or unable to discontinue their addiction to nicotine.

(19) There is evidence that harm reduction works and can be accomplished in a way that will not increase initiation or impede smoking cessation.

(20) Health-related agencies and organizations, both within the United States and abroad have already gone on record endorsing Harm Reduction as an approach to further reducing tobacco related illness and death.

(21) Current Federal policy requires tobacco product labeling that leaves the incorrect impression that all tobacco product present equal risk.

SEC. 3. PURPOSE.

The purposes of this Act are—

(1) to provide authority to the Tobacco Harm Reduction Center by recognizing it as the primary Federal regulatory authority with respect to tobacco products as provided for in this Act;

(2) to ensure that the Center has the authority to address issues of particular concern to public health officials, especially the use of tobacco by young people and dependence on tobacco;

(3) to authorize the Center to set national standards controlling the manufacture of tobacco products and the identity, public disclosure, and amount of ingredients used in such products;

(4) to provide new and flexible enforcement authority to ensure that there is effective oversight of the tobacco industry's efforts to develop, introduce, and promote less harmful tobacco products;

(5) to vest the Center with the authority to regulate the levels of tar, nicotine, and other harmful components of tobacco products;

(6) to ensure that consumers are better informed regarding the relative risks for death and disease between categories of tobacco products;

(7) to continue to allow the sale of tobacco products to adults in conjunction with measures to ensure that they are not sold or accessible to underage purchasers;

(8) to impose appropriate regulatory controls on the tobacco industry;

(9) to promote prevention, cessation, and harm reduction policies and regulations to reduce disease risk and the social costs associated with tobacco-related diseases;

(10) to provide authority to the Department of Health and Human Services to regulate tobacco products;

(11) to establish national policies that effectively reduce disease and death associated with cigarette smoking and other tobacco use;

(12) to establish national policies that encourage prevention, cessation, and harm reduction measures regarding the use of tobacco products;

(13) to encourage current cigarette smokers who will not quit to use noncombustible tobacco or nicotine products that have significantly less risk than cigarettes;

(14) to establish national policies that accurately and consistently inform adult tobacco consumers of significant differences in risk between respective tobacco products;

(15) to establish national policies that encourage and assist the development and awareness of noncombustible tobacco and nicotine products;

(16) to coordinate national and State prevention, cessation, and harm reduction programs;

(17) to impose measures to ensure tobacco products are not sold or accessible to underage purchasers; and

(18) to strengthen Federal and State legislation to prevent illicit trade in tobacco products.

SEC. 4. SCOPE AND EFFECT.

(a) INTENDED EFFECT.—Nothing in this Act (or an amendment made by this Act) shall be construed to—

(1) establish a precedent with regard to any other industry, situation, circumstance, or legal action;

(2) affect any action pending in Federal, State, or Tribal court, or any agreement, consent decree, or contract of any kind; or

(3) be applicable to tobacco products or component parts manufactured in the United States for export.

(b) AGRICULTURAL ACTIVITIES.—The provisions of this Act (or an amendment made by this Act) which authorize the Administrator to take certain actions with regard to tobacco and tobacco products shall not be construed to affect any authority of the Secretary of Agriculture under existing law regarding the growing, cultivation, or curing of raw tobacco.

(c) REVENUE ACTIVITIES.—The provisions of this Act (or an amendment made by this Act) which authorize the Administrator to take certain actions with regard to tobacco products shall not be construed to affect any authority of the Secretary of the Treasury under chapter 52 of the Internal Revenue Code of 1986.

SEC. 5. SEVERABILITY.

If any provision of this Act, the amendments made by this Act, or the application of any provision of this Act to any person or circumstance is held to be invalid, the remainder of this Act, the amendments made by this Act, and the application of the provisions of this Act to any other person or circumstance shall not be affected and shall continue to be enforced to the fullest extent possible.

SEC. 6. EFFECTIVE DATE.

Except as otherwise specifically provided, the effective date of this Act shall be the date of its enactment.

TITLE I—AUTHORITY OF THE TOBACCO HARM REDUCTION CENTER

SEC. 100. DEFINITIONS.

In this Act:

(1) The term ''Administrator'' means the chief executive of the Tobacco Regulatory Agency (the Agency responsible for administering and enforcing this Act and regulations promulgated pursuant to this Act).

(2) The term ''adult'' means any individual who has attained the minimum age under applicable State law to be an individual to whom tobacco products may lawfully be sold.

(3) The term ''adult-only facility'' means a facility or restricted area, whether open-air or enclosed, where the operator ensures, or has a reasonable basis to believe, that no youth is present. A facility or restricted area need not be permanently restricted to adults in order to constitute an adult-only facility, if the operator ensures, or has a reasonable basis to believe, that no youth is present during any period of operation as an adult-only facility.

(4) The term ''advertising'' means a communication to the general public by a tobacco product manufacturer, distributor, retailer, or its agents, which identifies a tobacco product by brand name and is intended by such manufacturer, distributor, retailer, or its agents to promote purchases of such tobacco product. Such term shall not include—

(A) any advertising or other communication in any tobacco trade publication or tobacco trade promotional material;

(B) the content of any scientific publication or presentation, or any patent application or other communication to the United States Patent and Trademark Office or any similar office in any other country;

(C) any corporate or financial report or financial communication;

(D) any communication to a lending institution or to securities holders;

(E) any communication not intended for public display or public exposure, except that a direct mailing or direct electronic communication of what otherwise is advertising shall be deemed to be advertising;

(F) any communication in, on, or within a factory, office, plant, warehouse, or other facility related to or associated with the development, manufacture, or storage of tobacco products;

(G) any communication to any governmental agency, body, official, or employee;

(H) any communication to any journalist, editor, Internet blogger, or other author;

(I) any communication in connection with litigation, including arbitration and like proceedings; or

(J) any editorial advertisement that addresses a public issue.

(5) The term ''affiliate'' means a person that directly or indirectly owns or controls, is owned or controlled by, or is under common ownership or control with, another person. The terms ''owns,'' ''is owned'', and ''ownership'' refer to ownership of an equity interest, or the equivalent thereof, of 50 percent or more.

(6) The term ''Agency'' means the Tobacco Regulatory Agency.

(7) The term ''age-verified adult'' means any individual who is an adult and—

(A) who has stated or acknowledged, after being asked, that he or she is an adult and a tobacco product user, and has presented proof of age identifying the individual and verifying that the individual is an adult; or

(B) whose status as an adult has been verified by a commercially available database of such information.

(8) The term ''annual report'' means a tobacco product manufacturer's annual report to the Agency, which provides ingredient information and nicotine yield ratings for each brand style that tobacco product manufacturer manufactures for commercial distribution domestically.

(9) The term ''brand name'' means a brand name of a tobacco product distributed or sold domestically, alone, or in conjunction with any other word, trademark, logo, symbol, motto, selling message, recognizable pattern of colors, or any other indicium of product identification identical or similar to, or identifiable with, those used for any domestic brand of tobacco product. The term shall not include the corporate name of any tobacco product manufacturer that does not, after the effective date of this Act, sell a brand style of tobacco product in the United States that includes such corporate name.

(10) The term ''brand name sponsorship'' means an athletic, musical, artistic, or other social or cultural event, series, or tour, with respect to which payment is made, or other consideration is provided, in exchange for use of a brand name or names—

(A) as part of the name of the event; or

(B) to identify, advertise, or promote such event or an entrant, participant, or team in such event in any other way.

(11) The term ''brand style'' means a tobacco product having a brand name, and distinguished by the selection of the tobacco, ingredients, structural materials, format, configuration, size, package, product descriptor, amount of tobacco, or yield of ''tar'' or nicotine.

(12) The term ''carton'' means a container into which packages of tobacco products are directly placed for distribution or sale, but does not include cases intended for shipping. Such term includes a carton containing 10 packages of cigarettes.

(13) The term ''cartoon'' means any drawing or other depiction of an object, person, animal, creature or any similar caricature that satisfies any of the following criteria:

(A) The use of comically exaggerated features.

(B) The attribution of human characteristics to animals, plants or other objects, or the similar use of anthropomorphic technique.

(C) The attribution of unnatural or extrahuman abilities, such as imperviousness to pain or injury, X-ray vision, tunneling at very high speeds, or transformation.

The term does not include any drawing or other depiction that, on the effective date of this Act, was in use in the United States in any tobacco product manufacturer's corporate logo or in any tobacco product manufacturer's tobacco product packaging.

(14) The term ''cigar'' has the meaning assigned that term by the Alcohol and Tobacco Tax and Trade Bureau in section 40.11 of title 27, Code of Federal Regulations.

(15) The term ''cigarette'' means—

(A) any roll of tobacco wrapped in paper or in any substance not containing tobacco; or

(B) any roll of tobacco wrapped in any substance containing tobacco which, because of the appearance of the roll of tobacco, the type of tobacco used in the filler, or its package or labeling, is likely to be offered to, or purchased by, consumers as a cigarette described in subparagraph (A).

(16) The term ''competent and reliable scientific evidence'' means evidence based on tests, analyses, research, or studies, conducted and evaluated in an objective manner by individuals qualified to do so, using procedures generally accepted in the relevant scientific disciplines to yield accurate and reliable results.

(17) The term ''distributor'' means any person who furthers the distribution of tobacco products, whether domestic or imported, at any point from the original place of manufacture to the person who sells or distributes the tobacco product to individuals for personal consumption. Common carriers, retailers, and those engaged solely in advertising are not considered distributors for purposes of this Act.

(18) The terms ''domestic'' and ''domestically'' mean within the United States, including activities within the United States involving advertising, marketing, distribution, or sale of tobacco products that are intended for consumption within the United States.

(19) The term ''human image'' means any photograph, drawing, silhouette, statue, model, video, likeness, or depiction of the appearance of a human being, or the appearance of any portion of the body of a human being.

(20) The term ''illicit tobacco product'' means any tobacco product intended for use by consumers in the United States—

(A) as to which not all applicable duties or taxes have been paid in full;

(B) that has been stolen, smuggled, or is otherwise contraband;

(C) that is counterfeit; or

(D) that has or had a label, labeling, or packaging stating, or that stated, that the product is or was for export only, or that it is or was at any time restricted by section 5704 of title 26, United States Code.

(21) The term ''illicit trade'' means any transfer, distribution, or sale in interstate commerce of any illicit tobacco product.

(22) The term ''immediate container'' does not include package liners.

(23) The term ''Indian tribe'' has the meaning assigned that term in section 4(e) of the Indian Self Determination and Education Assistance Act (25 U.S.C. 450b(e)).

(24) The term ''ingredient'' means tobacco and any substance added to tobacco to have an effect in the final tobacco product or when the final tobacco product is used by a consumer.

(25) The term ''International Organization for Standardization (ISO) testing regimen'' means the methods for measuring cigarette smoke yields, as set forth in the most recent version of ISO 3308, entitled ''Routine analytical cigarette-smoking machine—Definition of standard conditions''; ISO 4387, entitled ''Cigarettes—Determination of total and nicotine-free dry particulate matter using a routine analytical smoking machine''; ISO 10315, entitled ''Cigarettes—Determination of nicotine in smoke condensates—Gas-chromatographic method''; ISO 10362–1, entitled ''Cigarettes—Determination of water in smoke condensates—Part 1: Gas-chromatographic method''; and ISO 8454, entitled ''Cigarettes—Determination of carbon monoxide in the vapour phase of cigarette smoke—NDIR method''. A cigarette that does not burn down in accordance with the testing regimen standards may be measured under the same puff regimen using the number of puffs that such a cigarette delivers before it extinguishes, plus an additional three puffs, or with such other modifications as the Administrator may approve.

(26) The term ''interstate commerce'' means all trade, traffic, or other commerce—

(A) within the District of Columbia, or any territory or possession of the United States;

(B) between any point in a State and any point outside thereof;

(C) between points within the same State through any place outside such State; or

(D) over which the United States has jurisdiction.

(27) The term ''label'' means a display of written, printed, or graphic matter upon or applied securely to the immediate container of a tobacco product.

(28) The term ''labeling'' means all labels and other written, printed, or graphic matter (1) upon or applied securely to any tobacco product or any of its containers or wrappers, or (2) accompanying a tobacco product.

(29) The term ''little cigar'' has the meaning assigned that term by the Alcohol and Tobacco Tax and Trade Bureau in section 40.11 of title 27, Code of Federal Regulations.

(30) The term ''loose tobacco'' means any form of tobacco, alone or in combination with any other ingredient or material, that, because of its appearance, form, type, packaging, or labeling, is suitable for use and likely to be offered to, or purchased by, consumers as tobacco for making or assembling cigarettes, incorporation into pipes, or otherwise used by consumers to make any smoking article.

(31) The term ''manufacture'' means to design, manufacture, fabricate, assemble, process, package, or repackage, label, or relabel, import, or hold or store in a commercial quantity, but does not include—

(A) the growing, curing, de-stemming, or aging of tobacco; or

(B) the holding, storing or transporting of a tobacco product by a common carrier for hire, a public warehouse, a testing laboratory, a distributor, or a retailer.

(32) The term ''nicotine-containing product'' means a product intended for human consumption, other than a tobacco product, that contains added nicotine, produced and intended to be absorbed from the skin, mouth, or nose, or inhaled as a vapor or aerosol.

(33) The term ''outdoor advertising''—

(A) except as provided in subparagraph (B), means—

(i) billboards;

(ii) signs and placards in arenas, stadiums, shopping malls, and video game arcades (whether any of such are open air or enclosed), but not including any such sign or placard located in an adult-only facility; and

(iii) any other advertisements placed outdoors; and

(B) does not include—

(i) an advertisement on the outside of a tobacco product manufacturing facility; or

(ii) an advertisement that—

(I) is inside a retail establishment that sells tobacco products (other than solely through a vending machine or vending machines);

(II) is placed on the inside surface of a window facing outward; and

(III) is no larger than 14 square feet.

(34) The term ''package'' means a pack, box, carton, pouch, or container of any kind in which a tobacco product or tobacco products are offered for sale, sold, or otherwise distributed to consumers. The term ''package'' does not include an outer container used solely for shipping one or more packages of a tobacco product or tobacco products.

(35) The term ''person'' means any individual, partnership, corporation, committee, association, organization or group of persons, or other legal or business entity.

(36) The term ''proof of age'' means a driver's license or other form of identification that is issued by a governmental authority and includes a photograph and a date of birth of the individual.

(37) The term ''raw tobacco'' means tobacco in a form that is received by a tobacco product manufacturer as an agricultural commodity, whether in a form that is—

(A) natural, stem or leaf;

(B) cured or aged; or (3)

(C) as parts or pieces, but not in a reconstituted form, extracted pulp form, or extract form.

(38) The term ''reduced-exposure claim'' means a statement in advertising or labeling that a tobacco product provides a reduced exposure to one or more toxicants, as compared to an appropriate reference tobacco product within the same category of tobacco products. Such a statement must include the wording ''reduction in risk has not been demonstrated for this reduction in exposure''. A statement or representation that a tobacco product or the tobacco in a tobacco product contains ''no additives'' or is ''natural'' or that uses a substantially similar term is not a reduced-exposure claim if the advertising or labeling that contains such statement or representation also contains the disclosure required by section 108(h) of this Act.

(39) The term ''reduced-risk claim'' means a statement in advertising or labeling that a tobacco product provides a reduced risk of illness and death compared to cigarettes. A statement or representation that a tobacco product or the tobacco in a tobacco product contains ''no additives,'' or is ''natural,'' or that uses a substantially similar term is not a reduced-risk claim if the advertising or labeling that contains such statement or representation also contains the disclosure required by section 108(h).

(40) The term ''retailer'' means any person that—

(A) sells tobacco products to individuals for personal consumption; or

(B) operates a facility where the sale of tobacco products to individuals for personal consumption is permitted.

(41) The term ''sample'' means a tobacco product distributed to members of the public at no cost for the purpose of promoting the product, but excludes tobacco products distributed—

(A) in conjunction with the sale of other tobacco products;

(B) for market research, medical or scientific study or testing, or teaching;

(C) to persons employed in the trade;

(D) to adult consumers in response to consumer complaints; or

(E) to employees of the manufacturer of the tobacco product.

(42) The term ''small business'' means a tobacco product manufacturer that—

(A) has 150 or fewer employees; and

(B) during the 3-year period prior to the current calendar year, had an average annual gross revenue from tobacco products that did not exceed $40,000,000.

(43) The term ''smokeless tobacco product'' means any form of finely cut, ground, powdered, reconstituted, processed or shaped tobacco, leaf tobacco, or stem tobacco, whether or not combined with any other ingredient, whether or not in extract or extracted form, and whether or not incorporated within any carrier or construct, that is intended to be placed in the oral or nasal cavity, including dry snuff, moist snuff, and chewing tobacco.

(44) The term ''smoking article'' means any tobacco-containing article that is intended, when used by a consumer, to be burned or otherwise to employ heat to produce a vapor, aerosol or smoke that—

(A) incorporates components of tobacco or derived from tobacco; and

(B) is intended to be inhaled by the user.

(45) The term ''State'' means any State of the United States and, except as otherwise specifically provided, includes any Indian tribe or tribal organization, the District of Columbia, the Commonwealth of Puerto Rico, Guam, the Virgin Islands, American Samoa, Wake Island, Midway Island, Kingman Reef, Johnston Atoll, the Northern Marianas, and any other trust territory or possession of the United States.

(46) The term ''tar'' means nicotine-free dry particulate matter as defined in ISO 4387, entitled ''Cigarettes—Determination of total and nicotine-free dry particulate matter using a routine analytical smoking machine''.

(47) The term ''tobacco'' means a tobacco plant or any part of a harvested tobacco plant intended for use in the production of a tobacco product, including leaf, lamina, stem, or stalk, whether in green, cured, or aged form, whether in raw, treated, or processed form, and whether or not combined with other materials, including any by-product, extract, extracted pulp material, or any other material (other than purified nicotine) derived from a tobacco plant or any component thereof, and including strip, filler, stem, powder, and granulated, blended, or reconstituted forms of tobacco.

(48) The term ''tobacco product'' means—

(A) the singular of ''tobacco products'' as defined in section 5702(c) of the Internal Revenue Code of 1986;

(B) any other product that contains tobacco as a principal ingredient and that, because of its appearance, type, or the tobacco

used in the product, or its packaging and labeling, is likely to be offered to, or purchased by, consumers as a tobacco product as described in subparagraph (A); and

(C) any form of tobacco or any construct incorporating tobacco, intended for human consumption, whether by—

(i) placement in the oral or nasal cavity;

(ii) inhalation of vapor, aerosol, or smoke; or

(iii) any other means.

(49) The term ''tobacco product category'' means a type of tobacco product characterized by its composition, components, and intended use, and includes tobacco products classified as cigarettes, loose tobacco for roll-your-own tobacco products, little cigars, cigars, pipe tobacco, moist snuff, dry snuff, chewing tobacco, and other forms of tobacco products (which are treated in this Act collectively as a single category).

(50) The term ''tobacco product communication'' means any means, medium, or manner for providing information relating to any tobacco product, including face-to-face interaction, mailings by postal service or courier to an individual who is an addressee, and electronic mail to an individual who is an addressee.

(51) The term ''tobacco product manufacturer'' means an entity that directly—

(A) manufactures anywhere a tobacco product that is intended to be distributed commercially in the United States, including a tobacco product intended to be distributed commercially in the United States through an importer;

(B) is the first purchaser for resale in the United States of tobacco products manufactured outside the United States for distribution commercially in the United States; or

(C) is a successor or assign of any of the foregoing.

(52) The term ''toxicant'' means a chemical or physical agent that produces an adverse biological effect.

(53) The term ''transit advertisements'' means advertising on or within private or public vehicles and all advertisements placed at, on, or within any bus stop, taxi stand, transportation waiting area, train station, airport, or any similar location.

(54) The term ''tribal organization'' has the meaning assigned that term in section 4(1) of the Indian Self Determination and Education Assistance Act (25 U.S.C. 450b(1)).

(55) The term ''United States'' means the several States, as defined in this Act.

(56) The term ''vending machine'' means any mechanical, electric, or electronic self-service device that, upon insertion of money, tokens, or any other form of payment, automatically dispenses tobacco products.

(57) The term ''video game arcade'' means an entertainment establishment primarily consisting of video games (other than video games intended primarily for use by adults) or pinball machines.

(58) The term ''youth'' means any individual who in not an adult.

SEC. 101. CENTER AUTHORITY OVER TOBACCO PRODUCTS.

(a) IN GENERAL.—Tobacco products, including reduced risk tobacco products for which an order has been issued in accordance with section 117, shall be regulated by the Administrator under this Act.

(b) APPLICABILITY.—This Act shall apply to all cigarettes, cigarette tobacco, roll-your-own tobacco, and smokeless tobacco and to any other tobacco products that the Administrator by regulation deems to be subject to this Act.

(c) CENTER.—The Secretary of Health and Human Services shall establish within the Department of Health and Human Services the Tobacco Harm Reduction Center. The head of the Center shall be an Administrator, who shall assume the statutory authority conferred by this Act, perform the functions that relate to the subject matter of this Act, to conduct postmarket surveillance, research, and public education activities and have the authority to promulgate regulations for the efficient enforcement of this Act. In promulgating any regulations under such authority, in whole or in part or any regulation that is likely to have an annual effect on the economy of $50,000,000 or more or have a material adverse effect on adult users of tobacco products, tobacco product manufacturers, distributors, or retailers, the Administrator shall—

(1) determine the technological and economic ability of parties that would be required to comply with the regulation to comply with it;

(2) consider experience gained under any relevantly similar regulations at the Federal or State level;

(3) determine the reasonableness of the relationship between the costs of complying with such regulation and the public health benefits to be achieved by such regulation;

(4) determine the reasonable likelihood of measurable and substantial reductions in morbidity and mortality among individual tobacco users;

(5) determine the impact to United States tobacco producers and farm operations;

(6) determine the impact on the availability and use of tobacco products by minors; and

(7) determine the impact on illicit trade of tobacco products.

(d) LIMITATION OF AUTHORITY.—

(1) IN GENERAL.—The provisions of this Act shall not apply to tobacco leaf that is not in the possession of a manufacturer of tobacco products, or to the producers of tobacco leaf, including tobacco growers, tobacco warehouses, and tobacco grower cooperatives, nor shall any employee of the Center have any authority to enter onto a farm owned by a producer of tobacco leaf without the written consent of such producer.

(2) EXCEPTION.—Notwithstanding paragraph (1), if a producer of tobacco leaf is also a tobacco product manufacturer or controlled by a tobacco product manufacturer, the producer shall be subject to this Act in the producer's capacity as a manufacturer. The exception in this subparagraph shall not apply to a producer of tobacco leaf who grows tobacco under a contract with a tobacco product manufacturer and who is not otherwise engaged in the manufacturing process.

(3) RULE OF CONSTRUCTION.—Nothing in this Act shall be construed to grant the Administrator authority to promulgate regulations on any matter that involves the production of tobacco leaf or a producer thereof.

(e) RULEMAKING PROCEDURES.—Each rulemaking under this Act shall be in accordance with chapter 5 of title 5, United States Code.

(f) CONSULTATION PRIOR TO RULEMAKING.—Prior to promulgating rules under this Act, the Administrator shall endeavor to consult with other Federal agencies as appropriate.

SEC. 102. EXCLUSION OF OTHER REGULATORY PROGRAMS.

(a) EXCLUSION OF TOBACCO PRODUCTS AND NICOTINE-CONTAINING PRODUCTS FROM THE FEDERAL FOOD, DRUG, AND COSMETIC ACT.—No tobacco product and no nicotine-containing product shall be regulated as a food, drug, or device in accordance with section 201 (f), (g) or (h) or Chapter IV or V of the Federal Food, Drug, and Cosmetic Act, except that any tobacco product commercially distributed domestically and any nicotine-containing product commercially distributed domestically shall be subject to Chapter V of the Federal Food, Drug, and Cosmetic Act if the manufacturer or a distributor of such product markets it with an explicit claim that the product is intended for use in the cure, mitigation, treatment, or prevention of disease in man or other animals, within the meaning of section 201(g)(1)(C) or section 201(h)(2) of that Act.

(b) LIMITATION ON EFFECT OF THIS ACT.—Nothing in this Act shall be construed to—

(1) establish a precedent with regard to any other industry, situation, circumstance, or legal action; or

(2) affect any action pending in any Federal, State, or Tribal court, or any agreement, consent decree, or contract of any kind.

(c) EXCLUSIONS FROM AUTHORITY OF ADMINISTRATOR.—The authority granted to the Administrator under this Act shall not apply to—

(1) raw tobacco that is not in the possession or control of a tobacco product manufacturer;

(2) raw tobacco that is grown for a tobacco product manufacturer by a grower, and that is in the possession of that grower or of a person that is not a tobacco product manufacturer and is within the scope of subparagraphs (A) through(F) of paragraph (3); or

(3) the activities, materials, facilities, or practices of persons that are not tobacco product manufacturers and that are—

(A) producers of raw tobacco, including tobacco growers;

(B) tobacco warehouses, and other persons that receive raw tobacco from growers;

(C) tobacco grower cooperatives;

(D) persons that cure raw tobacco;

(E) persons that process raw tobacco; and

(F) persons that store raw tobacco for aging.

If a producer of raw tobacco is also a tobacco product manufacturer, an affiliate of a tobacco product manufacturer, or a person producing raw tobacco for a tobacco product manufacturer, then that producer shall be subject to this Act only to the extent of that producer's capacity as a tobacco product manufacturer.

SEC. 103. EXISTING FEDERAL STATUTES MAINTAINED.

Except as amended or repealed by this Act, all Federal statutes in effect as of the effective date of this Act that regulate tobacco, tobacco products, or tobacco product manufacturers shall remain in full force and effect. Such statutes include, without limitation—

(1) the Federal Cigarette Labeling and Advertising Act, sections 1331–1340 of title 15, United States Code, except that section 1335 of title 15, United States Code, is repealed;

(2) the Comprehensive Smokeless Tobacco Health Education Act of 1986, sections 4401–4408 of title 15, United States Code, except that section 4402(f) of title 15, United States Code, is repealed;

(3) section 300x–26 of title 42, United States Code; and

(4) those statutes authorizing regulation of tobacco, tobacco products, or tobacco product manufacturers by the Federal Trade Commission, the Department of Agriculture, the Environmental Protection Agency, the Internal Revenue Service, and the Alcohol and Tobacco Tax and Trade Bureau of the Department of the Treasury.

SEC. 104. PROCEEDINGS IN THE NAME OF THE UNITED STATES; SUBPOENAS; PREEMPTION OF STATE AND LOCAL LAW; NO PRIVATE RIGHT OF ACTION.

In furtherance of this Act:

(1) All proceedings for the enforcement, or to restrain violations, of this Act shall be by and in the name of the United States. Subpoenas for witnesses who are required to attend a court of the United States, in any district, may run into any other district in any

proceeding under this section. No State, or political subdivision thereof, may proceed or intervene in any Federal or State court under this Act or under any regulation promulgated under it, or allege any violation thereof except a violation by the Administrator. Nothing in this Act shall be construed to create a right of action by any private person for any violation of any provision of this Act or of any regulation promulgated under it.

(2) With respect to any subject matter addressed by this Act or by any regulation promulgated under it, no requirement or prohibition shall be imposed under State or local law upon any tobacco product manufacturer or distributor.

(3) Paragraph (2) shall not apply to any requirement or prohibition imposed under State or local law before the date of introduction of the bill that was enacted as this Act.

SEC. 105. ADULTERATED TOBACCO PRODUCTS.

A tobacco product shall be deemed to be adulterated—

(1) if it bears or contains any poisonous or deleterious substance other than—

(A) tobacco;

(B) a substance naturally present in tobacco;

(C) a pesticide or fungicide chemical residue in or on tobacco if such pesticide or fungicide chemical is registered by the Environmental Protection Agency for use on tobacco in the United States; or

(D) in the case of imported tobacco, a residue of a pesticide or fungicide chemical that—

(i) is approved for use in the country of origin of the tobacco; and

(ii) has not been banned, and the registration of which has not been canceled, by the Environmental Protection Agency for use on tobacco in the United States) that may render it injurious to health; but, in case the substance is not an added substance, such tobacco product shall not be considered adulterated under this subsection if the quantity of such substance in such tobacco product does not ordinarily render it injurious to health;

(2) if there is significant scientific agreement that, as a result of the tobacco it contains, the tobacco product presents a risk to human health that is materially higher than the risk presented by—

(A) such product on the effective date of this Act; or

(B) if such product was not distributed commercially domestically on that date, by comparable tobacco products of the same style and within the same category that were commercially distributed domestically on that date;

(3) if it has been prepared, packed, or held under unsanitary conditions whereby it may have become contaminated with filth;

(4) if its package is composed, in whole or in part, of any poisonous or deleterious substance that may render the contents injurious to health; or

(5) if its ''tar'' yield is in violation of section 111.

SEC. 106. MISBRANDED TOBACCO PRODUCTS.

A tobacco product shall be deemed to be misbranded—

(1) if its labeling is false or misleading in any particular;

(2) if in package form unless it bears a label containing—

(A) an identification of the type of product it is, by the common or usual name of such type of product;

(B) an accurate statement of the quantity of the contents in the package in terms of weight, measure, or numerical count, except that reasonable variations shall be permitted, and exemptions as to small packages shall be established by regulations promulgated by the Administrator;

(C) the name and place of business of the tobacco product manufacturer, packer, or distributor; and

(D) the information required by section 201(c) and (e) or section 202(c) and (e), as applicable;

(3) if any word, statement, or other information required by or under authority of this Act to appear on the label, labeling, or advertising is not prominently placed thereon with such conspicuousness (as compared with other words, statements, or designs on the label, labeling, or advertising, as applicable) and in such terms as to render it reasonably likely to be read and understood by the ordinary individual under customary conditions of purchase and use;

(4) if any word, statement, or other information is required by or under this Act to appear on the label, unless such word, statement, or other information also appears on the outside container or wrapper, if any, of the retail package of such tobacco product, or is easily legible through the outside container or wrapper;

(5) if it was manufactured, prepared, or processed in an establishment not duly registered under section 109, if it was not included in a list required by section 109, or if a notice or other information respecting it was not provided as required by section 109;

(6) if its packaging, labeling, or advertising is in violation of this Act or of an applicable regulation promulgated in accordance with this Act;

(7) if it contains tobacco or another ingredient as to which a required disclosure under this Act was not made;

(8) if it is labeled or advertised, or the tobacco contained in it is advertised, as—

(A) containing ''no additives,'' or any substantially similar term, unless the labeling or advertising, as applicable, also contains, clearly and prominently, the following disclosure: ''No additives in our tobacco does NOT mean safer.''; or

(B) being ''natural,'' or any substantially similar term, unless the labeling or advertising, as applicable, also contains, clearly and prominently, the following disclosure: ''Natural does NOT mean safer.'';

(9) if in its labeling or advertising a term descriptive of the tobacco in the tobacco product is used otherwise than in accordance with a sanction or approval granted by a Federal agency;

(10) if with respect to such tobacco product a disclosure required by section 603 was not made;

(11) if with respect to such tobacco product a certification required by section 803 was not submitted or is materially false or misleading; or

(12) if its manufacturer or distributor made with respect to it a claim prohibited by section 115.

SEC. 107. SUBMISSION OF HEALTH INFORMATION TO THE ADMINISTRATOR.

(a) REQUIREMENT.—Each tobacco product manufacturer or importer, or agents thereof, shall submit to the Administrator the following information:

(1) Not later than 18 months after the date of enactment of the Act, a listing of all ingredients, including tobacco, substances, compounds, and additives that are, as of such date, added by the manufacturer to the tobacco, paper, filter, or other part of each tobacco product by brand and by quantity in each brand and brand style.

(2) A description of the content, delivery, and form of nicotine in each tobacco product measured in milligrams of nicotine in accordance with regulations promulgated by the Administrator in accordance with section 4(e) of the Federal Cigarette Labeling and Advertising Act.

(3) Beginning 4 years after the date of enactment of this Act, a listing of all constituents, including smoke constituents as applicable, identified by the Administrator as harmful to health in each tobacco product, and as applicable in the smoke of each tobacco product, by brand and by quantity in each brand and subbrand.

(b) DATA SUBMISSION.—At the request of the Administrator, each tobacco product manufacturer or importer of tobacco products, or agents thereof, shall submit the following:

(1) Any or all documents (including underlying scientific information) relating to research activities, and research findings, conducted, supported, or possessed by the manufacturer (or agents thereof) on the health, toxicological, or physiologic effects of tobacco products and their constituents (including smoke constituents), ingredients, components, and additives.

(2) Any or all documents (including underlying scientific information) relating to research activities, and research findings, conducted, supported, or possessed by the manufacturer (or agents thereof) that relate to the issue of whether a significant reduction in risk to health from tobacco products can occur upon the employment of technology available to the manufacturer.

An importer of a tobacco product not manufactured in the United States shall supply the information required of a tobacco product manufacturer under this subsection.

(c) DATA LIST.—

(1) IN GENERAL.—Not later than 4 years after the date of enactment of the Act, and annually thereafter, the Administrator shall publish in a format that is understandable and not misleading to a lay person, and place on public display (in a manner determined by the Administrator) the list established under subsection (d).

(2) CONSUMER RESEARCH.—The Administrator shall conduct periodic consumer research to ensure that the list published under paragraph (1) is not misleading to lay persons. Not later than 5 years after the date of enactment of the Act, the Administrator shall submit to the appropriate committees of Congress a report on the results of such research, together with recommendations on whether such publication should be continued or modified.

(d) DATA COLLECTION.—Not later than 36 months after the date of enactment of this Act, the Administrator shall establish, and periodically revise as appropriate, a list of harmful constituents, including smoke constituents, to health in each tobacco product by brand and by quantity in each brand and subbrand.

SEC. 108. REGISTRATION AND LISTING.

(a) DEFINITIONS.—As used in this section:

(1) The term ''manufacture, preparation, or processing'' shall include repackaging or otherwise changing the container, wrapper, or label of any tobacco product package other than the carton in furtherance of the distribution of the tobacco product from the original place of manufacture to the person that makes final delivery or sale to the ultimate consumer or user, but shall not include the addition of a tax marking or other marking required by law to an already packaged tobacco product.

(2) The term ''name'' shall include in the case of a partnership the name of the general partner and, in the case of a privately held corporation, the name of the chief executive officer of the corporation and the State of incorporation.

(b) ANNUAL REGISTRATION.—Commencing one year after enactment, on or before December 31 of each year, every person that

owns or operates any establishment in any State engaged in the manufacture, preparation, or processing of a tobacco product or products for commercial distribution domestically shall register with the Administrator its name, places of business, and all such establishments.

(c) NEW PRODUCERS.—Every person upon first engaging, for commercial distribution domestically, in the manufacture, preparation, or processing of a tobacco product or products in any establishment that it owns or operates in any State shall immediately register with the Administrator its name, places of business, and such establishment.

(d) REGISTRATION OF FOREIGN ESTABLISHMENTS.—

(1) Commencing one year after enactment of this Act, on or before December 31 of each year, the person that, within any foreign country, owns or operates any establishment engaged in the manufacture, preparation, or processing of a tobacco product that is imported or offered for import into the United States shall, through electronic means or other means permitted by the Administrator, register with the Administrator the name and place of business of each such establishment, the name of the United States agent for the establishment, and the name of each importer of such tobacco product in the United States that is known to such person.

(2) Such person also shall provide the information required by subsection (j), including sales made by mail, or through the Internet, or other electronic means.

(3) The Administrator is authorized to enter into cooperative arrangements with officials of foreign countries to ensure that adequate and effective means are available for purposes of determining, from time to time, whether tobacco products manufactured, prepared, or processed by an establishment described in paragraph (1), if imported or offered for import into the United States, shall be refused admission on any of the grounds set forth in section 708.

(e) ADDITIONAL ESTABLISHMENTS.—Every person duly registered in accordance with the foregoing subsections of this section shall immediately register with the Administrator any additional establishment that it owns or operates and in which it begins the manufacture, preparation, or processing of a tobacco product or products for commercial distribution domestically or for import into the United States.

(f) EXCLUSIONS FROM APPLICATION OF THIS SECTION.—The foregoing subsections of this section shall not apply to—

(1) persons that manufacture, prepare, or process tobacco products solely for use in research, teaching, chemical or biological analysis, or export; or

(2) such other classes of persons as the Administrator may by regulation exempt from the application of this section upon a finding that registration by such classes of persons in accordance with this section is not necessary for the protection of the public health.

(g) INSPECTION OF PREMISES.—Every establishment registered with the Administrator pursuant to this section shall be subject to inspection pursuant to section 706; and every such establishment engaged in the manufacture, preparation, or processing of a tobacco product or products shall be so inspected by one or more officers or employees duly designated by the Administrator at least once in the two-year period beginning with the date of registration of such establishment pursuant to this section and at least once in every successive two-year period thereafter, except that inspection of establishments outside the United States may be conducted by other personnel pursuant to a cooperative arrangement under subsection (d)(3).

(h) FILING OF LISTS OF TOBACCO PRODUCTS MANUFACTURED, PREPARED, OR PROCESSED BY REGISTRANTS; STATEMENTS; ACCOMPANYING DISCLOSURES.—

(1) Every person that registers with the Administrator under subsection (b), (c), (d), or (e) shall, at the time of registration under any such subsection, file with the Administrator a list of all brand styles (with each brand style in each list listed by the common or usual name of the tobacco product category to which it belongs and by any proprietary name) that are being manufactured, prepared, or processed by such person for commercial distribution domestically or for import into the United States, and that such person has not included in any list of tobacco products filed by such person with the Administrator under this paragraph or paragraph (2) before such time of registration. Such list shall be prepared in such form and manner as the Administrator may prescribe, and shall be accompanied by the label for each such brand style and a representative sampling of any other labeling and advertising for each;

(2) Each person that registers with the Administrator under this section shall report to the Administrator each August for the preceding six-month period from January through June, and each February for the preceding six-month period form July through December, following information:

(A) A list of each brand style introduced by the registrant for commercial distribution domestically or for import into the United States that has not been included in any list previously filed by such registrant with the Administrator under this subparagraph or paragraph (1). A list under this subparagraph shall list a brand style by the common or usual name of the tobacco product category to which it belongs and by any proprietary name, and shall be accompanied by the other information required by paragraph (1).

(B) If since the date the registrant last made a report under this paragraph (or if such registrant has not previously made a report under this paragraph, since the effective date of this Act) such registrant has discontinued the manufacture, preparation, or processing for commercial distribution domestically or for import into the United States of a brand style included in a list filed by such registrant under subparagraph (A) or paragraph (1), notice of such discontinuance, the date of such discontinuance, and the identity (by the common or usual name of the tobacco product category to which it belongs and by any proprietary name) of such tobacco product.

(C) If, since the date the registrant reported pursuant to subparagraph (B) a notice of discontinuance of a tobacco product, the registrant has resumed the manufacture, preparation, or processing for commercial distribution domestically or for import into the United States of that brand style, notice of such resumption, the date of such resumption, the identity of such brand style (by the common or usual name of the tobacco product category to which it belongs and by any proprietary name), and the other information required by paragraph (1), unless the registrant has previously reported such resumption to the Administrator pursuant to this subparagraph.

(D) Any material change in any information previously submitted pursuant to this paragraph (2) or paragraph (1).

(i) ELECTRONIC REGISTRATION.—Registrations under subsections (b), (c), (d), and (e) (including the submission of updated information) shall be submitted to the Administrator by electronic means, unless the Administrator grants a request for waiver of such requirement because use of electronic means is not reasonable for the person requesting such waiver.

SEC. 109. GENERAL PROVISIONS RESPECTING CONTROL OF TOBACCO PRODUCTS.

(a) IN GENERAL.—Any requirement established by or under section 106, 107, or 113 applicable to a tobacco product shall apply to such tobacco product until the applicability of the requirement to the tobacco product has been changed by action taken under section 111, section 114, section 115, or subsection (d) of this section, and any requirement established by or under section 106, 107, or 113 which is inconsistent with a requirement imposed on such tobacco product under section 111, section 114, section 115, or subsection (d) of this section shall not apply to such tobacco product.

(b) INFORMATION ON PUBLIC ACCESS AND COMMENT.—Each notice of proposed rulemaking or other notification under section 111, 112, 113, 114, or 115 or under this section, any other notice which is published in the Federal Register with respect to any other action taken under any such section and which states the reasons for such action, and each publication of findings required to be made in connection with rulemaking under any such section shall set forth—

(1) the manner in which interested persons may examine data and other information on which the notice or findings is based; and

(2) the period within which interested persons may present their comments on the notice or findings (including the need therefore) orally or in writing, which period shall be at least 60 days but may not exceed 90 days unless the time is extended by the Administrator by a notice published in the Federal Register stating good cause therefore.

(c) LIMITED CONFIDENTIALITY OF INFORMATION.—Any information reported to or otherwise obtained by the Administrator or the Administrator's representative under section 107, 108, 111, 112, 113, 114, 115, or 504, or under subsection (e) or (f) of this section, which is exempt from disclosure under subsection (a) of section 552 of title 5, United States Code, by reason of subsection (b)(4) of that section shall be considered confidential and shall not be disclosed, except that the information may be disclosed to other officers or employees concerned with carrying out this Act, or when relevant in any proceeding under this Act.

(d) RESTRICTIONS.—

(1) IN GENERAL.—The Administrator may issue regulations, consistent with this Act, regarding tobacco products if the Administrator determines that such regulation would be appropriate for the protection of the public health. The finding as to whether such regulation would be appropriate for the protection of the public health shall be determined with respect to the risks and benefits to the users of the tobacco product, and taking into account that the standard is reasonably likely to result in measurable and substantial reductions in morbidly and mortality among individual tobacco users.

(2) LABEL STATEMENTS.—The label of a tobacco product shall bear such appropriate statements of the restrictions required by a regulation under subsection (a) as the Administrator may in such regulation prescribe.

(e) GOOD MANUFACTURING PRACTICE REQUIREMENTS.—

(1) METHODS, FACILITIES, AND CONTROLS TO CONFORM.—

(A) IN GENERAL.—In applying manufacturing restrictions to tobacco, the Administrator shall, in accordance with subparagraph (B), prescribe regulations (which may differ based on the type of tobacco product involved) requiring that the methods used in, and the facilities and controls used for, the

manufacture, preproduction design validation (including a process to assess the performance of a tobacco product), packing, and storage of a tobacco product conform to current good manufacturing practice, or hazard analysis and critical control point methodology, as prescribed in such regulations to assure that the public health is protected and that the tobacco product is in compliance with this Act. Such regulations may provide for the testing of raw tobacco for pesticide chemical residues after a tolerance for such chemical residues has been established.

(B) REQUIREMENTS.—The Administrator shall—

(i) before promulgating any regulation under subparagraph (A), afford the Tobacco Products Scientific Advisory Committee an opportunity to submit recommendations with respect to the regulation proposed to be promulgated;

(ii) before promulgating any regulation under subparagraph (A), afford opportunity for an oral hearing;

(iii) provide the Tobacco Products Scientific Advisory Committee a reasonable time to make its recommendation with respect to proposed regulations under subparagraph (A); and

(iv) in establishing the effective date of a regulation promulgated under this subsection, take into account the differences in the manner in which the different types of tobacco products have historically been produced, the financial resources of the different tobacco product manufacturers, and the state of their existing manufacturing facilities, and shall provide for a reasonable period of time for such manufacturers to conform to good manufacturing practices but no earlier than four years from date of enactment.

(C) ADDITIONAL SPECIAL RULE.—A tobacco product manufactured in or imported into the United States shall not contain foreign-grown flue-cured or burley tobacco that—

(i) was knowingly grown or processed using a pesticide chemical that is not approved under applicable Federal law for use in domestic tobacco farming and processing; or

(ii) in the case of a pesticide chemical that is so approved, was grown or processed using the pesticide chemical in a manner inconsistent with the approved labeling for use of the pesticide chemical in domestic tobacco farming and processing.

(D) EXCLUSION.—Subparagraph (C)(ii) shall not apply to tobacco products manufactured with foreign-grown flue-cured or burley tobacco so long as that foreign grown tobacco was either—

(i) in the inventory of a manufacturer prior to the effective date, or

(ii) planted by the farmer prior to the effective date of this Act and utilized by the manufacturer no later than 3 years after the effective date.

(E) SETTING OF MAXIMUM RESIDUE LIMITS.—The Administrator shall adopt the following pesticide residue standards:

Pesticide residue standards

The maximum concentration of residues of the following pesticides allowed in flue-cured or burley tobacco, expressed as parts by weight of the residue per one million parts by weight of the tobacco (PPM) are:

CHLORDANE.....3.0

DIBROMOCHLOROPROPANE (DBCP).....1.0

DICAMBA (Temporary).... 5.0

ENDRIN....0.1

ETHYLENE DIBROMIDE (EDB)....0.1

FORMOTHION.....0.5

HEXACHLOROBENZENE (HCB)....0.1

METHOXYCHLOR.....0.1

TOXAPHENE.....0.3

2,4-D (Temporary).....5.0

2,4,5-T.....0.1

Sum of ALDRIN and DIELDRIN.....0.1

Sum of CYPERMETHRIN and PERMETHRIN (Temporary).....3.0

Sum of DDT, TDE (DDD), and DDE 0.4

Sum of HEPTACHLOR and HEPTACHLOR EPOXIDE.....0.1

(F) MAXIMUM RESIDUE LIMITS.—The Administrator shall adopt regulations within one year of the effective date of this Act to establish maximum residue limits for pesticides identified under subparagraph (E) but not included in the table of such subparagraph to account for the fact that weather and agronomic conditions will cause pesticides identified in subparagraph (E) to be detected in foreign-grown tobacco even where the farmer has not knowingly added such pesticide.

(2) EXEMPTIONS; VARIANCES.—

(A) PETITION.—Any person subject to any requirement prescribed under paragraph (1) may petition the Administrator for a permanent or temporary exemption or variance from such requirement. Such a petition shall be submitted to the Administrator in such form and manner as the Administrator shall prescribe and shall—

(i) in the case of a petition for an exemption from a requirement, set forth the basis for the petitioner's determination that compliance with the requirement is not required to assure that the tobacco product will be in compliance with this Act;

(ii) in the case of a petition for a variance from a requirement, set forth the methods proposed to be used in, and the facilities and controls proposed to be used for, the manufacture, packing, and storage of the tobacco product in lieu of the methods, facilities, and controls prescribed by the requirement; and

(iii) contain such other information as the Administrator shall prescribe.

(B) REFERRAL TO THE TOBACCO PRODUCTS SCIENTIFIC ADVISORY COMMITTEE.—The Administrator may refer to the Tobacco Products Scientific Advisory Committee any petition submitted under subparagraph (A). The Tobacco Products Scientific Advisory Committee shall report its recommendations to the Administrator with respect to a petition referred to it within 60 days after the date of the petition's referral. Within 60 days after—

(i) the date the petition was submitted to the Administrator under subparagraph (A); or

(ii) the day after the petition was referred to the Tobacco Products Scientific Advisory Committee,

whichever occurs later, the Administrator shall by order either deny the petition or approve it.

(C) APPROVAL.—The Administrator may approve—

(i) a petition for an exemption for a tobacco product from a requirement if the Administrator determines that compliance with such requirement is not required to assure that the tobacco product will be in compliance with this Act; and

(ii) a petition for a variance for a tobacco product from a requirement if the Administrator determines that the methods to be used in, and the facilities and controls to be used for, the manufacture, packing, and storage of the tobacco product in lieu of the methods, facilities, and controls prescribed by the requirement are sufficient to assure that the tobacco product will be in compliance with this Act.

(D) CONDITIONS.—An order of the Administrator approving a petition for a variance shall prescribe such conditions respecting the methods used in, and the facilities and controls used for, the manufacture, packing, and storage of the tobacco product to be granted the variance under the petition as may be necessary to assure that the tobacco product will be in compliance with this Act.

(E) HEARING.—After the issuance of an order under subparagraph (B) respecting a petition, the petitioner shall have an opportunity for an informal hearing on such order.

(3) COMPLIANCE.—Compliance with requirements under this subsection shall not be required before the end of the 3-year period following the date of enactment of this Act.

(f) RESEARCH AND DEVELOPMENT.—The Administrator may enter into contracts for research, testing, and demonstrations respecting tobacco products and may obtain tobacco products for research, testing, and demonstration purposes.

SEC. 110. SMOKING ARTICLE STANDARDS.

(a) IN GENERAL.—

(1) RESTRICTIONS ON DESCRIPTORS USED IN MARKETING OF CIGARETTES.—

(A) IN GENERAL.—Except as provided in subparagraph (B), no person shall use, with respect to any cigarette brand style commercially distributed domestically, on the portion of the package of such cigarette brand style that customarily is visible to consumers before purchase, or in advertising of such cigarette brand style any of the following as a descriptor of any cigarette brand style—

(i) the name of any candy or fruit;

(ii) the word ''candy,'' ''citrus,'' ''cream,'' ''fruit,'' ''sugar,'' ''sweet,'' ''tangy,'' or ''tart,''; or

(iii) any extension or variation of any of the words ''candy,'' ''citrus,'' ''cream,'' ''fruit,'' ''sugar,'' ''sweet,'' ''tangy,'' or ''tart,'' including but not limited to ''creamy,'' or ''fruity.''

(B) LIMITATION.—Subparagraph (A) shall not apply to the use of the following words or to any extension or variation of any of them: ''clove'' and ''menthol''.

(C) SCENTED MATERIALS.—No person shall use, in the advertising or labeling of any cigarette commercially distributed domestically, any scented materials, except in an adult-only facility.

(D) DEFINITIONS.—In this section:

(i) The term ''candy'' means a confection made from sugar or sugar substitute, including any confection identified generically or by brand, and shall include the words ''cacao,'' ''chocolate,'' ''cinnamon,'' ''cocoa,'' ''honey,'' ''licorice,'' ''maple,'' ''mocha,'' and ''vanilla.''

(ii) The term ''fruit'' means any fruit identified by generic name, type, or variety, including but not limited to ''apple,'' ''banana,'' ''cherry,'' and ''orange.'' The term ''fruit'' does not include words that identify seeds, nuts or peppers, or types or varieties thereof or words that are extensions or variations of such words.

(2) SMOKING ARTICLE STANDARDS.—

(A) IN GENERAL.—The Administrator may adopt smoking article standards in addition to those in paragraph (1) if the Administrator finds that a smoking article standard is appropriate for the protection of the public health.

(B) DETERMINATIONS.—

(i) CONSIDERATIONS.—In making a finding described in subparagraph (A), the Administrator shall consider scientific evidence concerning—

(I) the risks and benefits to the users of smoking articles of the proposed standard; and

(II) that the standard is reasonably likely to result in measurable and substantial reductions in morbidity and mortality among individual tobacco users.

(ii) ADDITIONAL CONSIDERATIONS.—In the event that the Administrator makes a determination, set forth in a proposed smoking article standard in a proposed rule, that it is

appropriate for the protection of public health to require the reduction or elimination of an additive, constituent (including a smoke constituent), or other component of a smoking article because the Administrator has found that the additive, constituent, or other component is harmful, any party objecting to the proposed standard on the ground that the proposed standard will not reduce or eliminate the risk of illness or injury may provide for the Administrator's consideration scientific evidence that demonstrates that the proposed standard will not reduce or eliminate the risk of illness or injury.

(3) CONTENT OF SMOKING ARTICLE STANDARDS.—A smoking article standard established under this section for a smoking article—

(A) may include provisions that are appropriate for the protection of the public health, including provisions, where appropriate—

(i) for ''tar'' and nicotine yields of the product;

(ii) for the reduction of other constituents, including smoke constituents, or harmful components of the product; or

(iii) relating to any other requirement under subparagraph (B); and

(B) may, where appropriate for the protection of the public health, include—

(i) provisions respecting the construction, components, ingredients, additives, constituents, including smoke constituents, and properties of the smoking article;

(ii) provisions for the testing (on a sample basis or, if necessary, on an individual basis) of the smoking article;

(iii) provisions for the measurement of the smoking article characteristics of the smoking article; and

(iv) provisions requiring that the results of each or of certain of the tests of the smoking article required to be made under clause (ii) show that the smoking article is in conformity with the portions of the standard for which the test or tests were required.

(4) PERIODIC REEVALUATION OF SMOKING ARTICLE STANDARDS.—The Administrator may provide for periodic evaluation of smoking article standards established under this section to determine whether such standards should be changed to reflect new medical, scientific, or other technological data.

(5) CIGARETTE ''TAR'' LIMITS.—

(A) NO INCREASE IN ''TAR'' YIELDS.—No cigarette manufacturer shall distribute for sale domestically a brand style of cigarettes that generates a ''tar'' yield greater than the ''tar'' yield of that brand style of cigarettes on the date of introduction of this Act, as determined by the ISO smoking regimen and its associated tolerances. The ''tar'' tolerances for cigarettes with ISO ''tar'' yields in the range of 1 to 20 milligrams per cigarette, based on variations arising from sampling procedure, test method, and sampled product, itself, are the greater of plus or minus—

(i) 15 percent; or

(ii) 1 milligram per cigarette.

(B) LIMIT ON NEW CIGARETTES.—After the effective date of this Act, no cigarette manufacturer shall manufacture for commercial distribution domestically a brand style of cigarettes that both—

(i) was not in commercial distribution domestically on the effective date of this Act, and

(ii) generates a ''tar'' yield of greater than 20 milligrams per cigarette as determined by the ISO smoking regimen and its associated tolerances.

(C) LIMIT ON ALL CIGARETTES.—After December 31, 2010, no cigarette manufacturer shall manufacture for commercial distribution domestically a brand style of cigarettes that generates a ''tar'' yield greater than 20 milligrams per cigarette as determined by the ISO smoking regimen and its associated tolerances.

(D) REVIEW BY ADMINISTRATOR.—After the effective date of this Act, the Administrator shall evaluate the available scientific evidence addressing the potential relationship between historical ''tar'' yield values and risk of harm to smokers. If upon a review of that evidence, and after consultation with technical experts of the Tobacco Harm Reduction Center and the Centers for Disease Control and Prevention and notice and an opportunity for public comment, the Administrator determines, that a reduction in ''tar'' yield may reasonably be expected to provide a meaningful reduction of the risk or risks of harm to smokers, the Administrator shall issue an order that—

(i) provides that no cigarette manufacturer shall manufacture for commercial distribution domestically a cigarette that generates a ''tar'' yield that exceeds 14 milligrams as determined by the ISO smoking regimen and its associated tolerances; and

(ii) provides a reasonable time for manufacturers to come into compliance with such prohibition.

(6) INVOLVEMENT OF OTHER AGENCIES; INFORMED PERSONS.—In carrying out duties under this section, the Administrator shall endeavor to—

(A) use personnel, facilities, and other technical support available in other Federal agencies;

(B) consult with other Federal agencies concerned with standard setting and other nationally or internationally recognized standard-setting entities; and

(C) invite appropriate participation, through joint or other conferences, workshops, or other means, by informed persons representative of scientific, professional, industry, agricultural, or consumer organizations who in the Administrator's judgment can make a significant contribution.

(b) CONSIDERATIONS BY ADMINISTRATOR.—

(1) TECHNICAL ACHIEVABILITY.—The Administrator shall consider information submitted in connection with a proposed standard regarding the technical achievability of compliance with such standard.

(2) OTHER CONSIDERATIONS.—The Administrator shall consider all other information submitted in connection with a proposed standard, such as the creation of a significant demand for contraband or other tobacco products that do not meet the requirements of this Act and the significance of such demand.

(c) PROPOSED STANDARDS.—

(1) IN GENERAL.—The Administrator shall publish in the Federal Register a notice of proposed rulemaking for the establishment, amendment, or revocation of any smoking article standard.

(2) REQUIREMENTS OF NOTICE.—A notice of proposed rulemaking for the establishment or amendment of a smoking article standard shall—

(A) set forth a finding with supporting justification that the smoking article standard is appropriate for the protection of the public health;

(B) invite interested persons to submit a draft or proposed smoking article standard for consideration by the Administrator;

(C) invite interested persons to submit comments on structuring the standard so that it does not advantage foreign-grown tobacco over domestically grown tobacco; and

(D) invite the Secretary of Agriculture to provide any information or analysis which the Secretary of Agriculture believes is relevant to the proposed smoking article standard.

(3) FINDING.—A notice of proposed rulemaking for the revocation of a smoking article standard shall set forth a finding with supporting justification that the smoking article standard is no longer appropriate for the protection of the public health.

(4) COMMENT.—The Administrator shall provide for a comment period of not less than 90 days.

(d) PROMULGATION.—

(1) IN GENERAL.—After the expiration of the period for comment on a notice of proposed rulemaking published under subsection (c) respecting a standard and after consideration of comments submitted under subsections (b) and (c) and any report from the Tobacco Products Scientific Advisory Committee, if the Administrator determines that the standard would be appropriate for the protection of the public health, the Administrator shall—

(A) promulgate a regulation establishing a smoking article standard and publish in the Federal Register findings on the matters referred to in subsection (c); or

(B) publish a notice terminating the proceeding for the development of the standard together with the reasons for such termination.

(2) EFFECTIVE DATE.—A regulation establishing a smoking article standard shall set forth the date or dates upon which the standard shall take effect, but no such regulation may take effect before 1 year after the date of its publication unless the Administrator determines that an earlier effective date is necessary for the protection of the public health. Such date or dates shall be established so as to minimize, consistent with the public health, economic loss to, and disruption or dislocation of, domestic and international trade. In establishing such effective date or dates, the Administrator shall consider information submitted in connection with a proposed product standard by interested parties, including manufacturers and tobacco growers, regarding the technical achievability of compliance with the standard, and including information concerning the existence of patents that make it impossible to comply in the timeframe envisioned in the proposed standard.

(3) LIMITATION ON POWER GRANTED.—Because of the importance of a decision of the Administrator to issue a regulation—

(A) banning cigarettes, smokeless smoking articles, little cigars, cigars other than little cigars, pipe tobacco, or roll-your-own smoking articles;

(B) requiring the reduction of ''tar'' or nicotine yields of a smoking article to zero;

(C) prohibiting the sale of any smoking article in face-to-face transactions by a specific category of retail outlets;

(D) establishing a minimum age of sale of smoking articles to any person older than 18 years of age; or

(E) requiring that the sale or distribution of a smoking article be limited to the written or oral authorization of a practitioner licensed by law to prescribe medical products, the Administrator is prohibited from taking such actions under this Act.

(4) MATCHBOOKS.—For purposes of any regulations issued by the Administrator under this Act, matchbooks of conventional size containing not more than 20 paper matches, and which are customarily given away for free with the purchase of smoking articles, shall be considered as adult-written publications which shall be permitted to contain advertising.

(5) AMENDMENT; REVOCATION.—

(A) AUTHORITY.—The Administrator, upon the Administrator's own initiative or upon petition of an interested person, may by a regulation, promulgated in accordance with the requirements of subsection (c) and paragraph (2), amend or revoke a smoking article standard.

(B) EFFECTIVE DATE.—The Administrator may declare a proposed amendment of a smoking article standard to be effective on and after its publication in the Federal Register and until the effective date of any final action taken on such amendment if the Administrator determines that making it so effective is in the public interest.

(6) REFERRAL TO ADVISORY COMMITTEE.—

(A) IN GENERAL.—The Administrator shall refer a proposed regulation for the establishment, amendment, or revocation of a smoking article standard to the Tobacco Products Scientific Advisory Committee for a report and recommendation with respect to any matter involved in the proposed regulation which requires the exercise of scientific judgment.

(B) INITIATION OF REFERRAL.—The Administrator shall make a referral under this paragraph—

(i) on the Administrator's own initiative; or

(ii) upon the request of an interested person that—

(I) demonstrates good cause for the referral; and

(II) is made before the expiration of the period for submission of comments on the proposed regulation.

(C) PROVISION OF DATA.—If a proposed regulation is referred under this paragraph to the Tobacco Products Scientific Advisory Committee, the Administrator shall provide the Advisory Committee with the data and information on which such proposed regulation is based.

(D) REPORT AND RECOMMENDATION.—The Tobacco Products Scientific Advisory Committee shall, within 90 days after the referral of a proposed regulation under this paragraph and after independent study of the data and information furnished to it by the Administrator and other data and information before it, submit to the Administrator a report and recommendation respecting such regulation, together with all underlying data and information and a statement of the reason or basis for the recommendation.

(E) PUBLIC AVAILABILITY.—The Administrator shall make a copy of each report and recommendation under subparagraph (D) publicly available.

SEC. 111. NOTIFICATION AND OTHER REMEDIES.

(a) NOTIFICATION.—If the Administrator determines that—

(1) a tobacco product which is introduced or delivered for introduction into interstate commerce for commercial distribution presents an unreasonable risk of substantial harm materially above the risk for death and disease of tobacco products currently in interstate commerce, to the public health; and

(2) notification under this subsection is necessary to eliminate the unreasonable risk of such harm and no more practicable means is available under the provisions of this Act (other than this section) to eliminate such risk,

the Administrator may issue such order as may be necessary to assure that adequate notification is provided in an appropriate form, by the persons and means best suited under the circumstances involved, to all persons who should properly receive such notification in order to eliminate such risk. The Administrator may order notification by any appropriate means, including public service announcements. Before issuing an order under this subsection, the Administrator shall consult with the persons who are to give notice under the order.

(b) NO EXEMPTION FROM OTHER LIABILITY.—Compliance with an order issued under this section shall not relieve any person from liability under Federal or State law. In awarding damages for economic loss in an action brought for the enforcement of any such liability, the value to the plaintiff in such action of any remedy provided under such order shall be taken into account.

(c) RECALL AUTHORITY.—

(1) IN GENERAL.—If the Administrator finds that there is a reasonable probability that a tobacco product contains a manufacturing or other defect not ordinarily contained in tobacco products on the market that would cause serious, acute adverse health consequences or death, the Administrator shall issue an order requiring the appropriate person (including the manufacturers, importers, distributors, or retailers of the tobacco product) to immediately cease distribution of such tobacco product. The order shall provide the person subject to the order with an opportunity for an informal hearing, to be held not later than 10 days after the date of the issuance of the order, on the actions required by the order and on whether the order should be amended to require a recall of such tobacco product. If, after providing an opportunity for such a hearing, the Administrator determines that inadequate grounds exist to support the actions required by the order, the Administrator shall vacate the order.

(2) AMENDMENT OF ORDER TO REQUIRE RECALL.—

(A) IN GENERAL.—If, after providing an opportunity for an informal hearing under paragraph (1), the Administrator determines that the order should be amended to include a recall of the tobacco product with respect to which the order was issued, the Administrator shall, except as provided in subparagraph (B), amend the order to require a recall. The Administrator shall specify a timetable in which the tobacco product recall will occur and shall require periodic reports to the Administrator describing the progress of the recall.

(B) NOTICE.—An amended order under subparagraph (A)—

(i) shall not include recall of a tobacco product from individuals; and

(ii) shall provide for notice to persons subject to the risks associated with the use of such tobacco product.

In providing the notice required by clause (ii), the Administrator may use the assistance of retailers and other persons who distributed such tobacco product. If a significant number of such persons cannot be identified, the Administrator shall notify such persons under section 705(b).

(3) REMEDY NOT EXCLUSIVE.—The remedy provided by this subsection shall be in addition to remedies provided by subsection (a).

SEC. 112. RECORDS AND REPORTS ON TOBACCO PRODUCTS.

Every person who is a tobacco product manufacturer or importer of a tobacco product shall establish and maintain such records, make such reports, and provide such information, as the Administrator may by regulation reasonably require to assure that such tobacco product is not adulterated or misbranded.

SEC. 113. APPLICATION FOR REVIEW OF CERTAIN SMOKING ARTICLES.

(a) IN GENERAL.—

(1) NEW SMOKING ARTICLE DEFINED.—For purposes of this section the term ''new smoking article'' means—

(A) any smoking article that was not commercially marketed in the United States as of the date of enactment of this Act; and

(B) any smoking article that incorporates a significant modification (including changes in design, component, part, or constituent, including a smoke constituent, or in the content, delivery or form of nicotine, or other additive or ingredient) of a smoking article where the reduced product was commercially marketed in the United States after the date of enactment of this Act.

(2) PREMARKET REVIEW REQUIRED.—

(A) NEW PRODUCTS.—An order under subsection (c)(1)(A) for a new smoking article is required unless the product—

(i) is substantially equivalent to a smoking article commercially marketed in the United States as of date of enactment of this Act; and

(ii) is in compliance with the requirements of this Act.

(B) CONSUMER TESTING.—This section shall not apply to smoking articles that are provided to adult tobacco consumers for purposes of consumer testing. For purposes of this section, the term ''consumer testing'' means an assessment of smoking articles that is conducted by or under the control and direction of a manufacturer for the purpose of evaluating consumer acceptance of such smoking articles, utilizing only the quantity of cigarettes that is reasonably necessary for such assessment

(3) SUBSTANTIALLY EQUIVALENT DEFINED.—

(A) IN GENERAL.—In this section, the term ''substantially equivalent'' or ''substantial equivalence'' means, with respect to the smoking article being compared to the predicate smoking article, that the Administrator by order has found that the smoking article—

(i) has the same general characteristics as the predicate smoking article; or

(ii) has different characteristics and the information submitted contains information, including clinical data if deemed necessary by the Administrator, that demonstrates that it is not appropriate to regulate the product under this section because the product does not raise different questions of public health for the consumer of the product.

(B) CHARACTERISTICS.—In subparagraph (A), the term ''characteristics'' means the materials, ingredients, design, composition, heating source, or other features of a smoking article.

(C) LIMITATION.—A smoking article may not be found to be substantially equivalent to a predicate smoking article that has been removed from the market at the initiative of the Administrator or that has been determined by a judicial order to be misbranded or adulterated.

(4) HEALTH INFORMATION.—As part of a submission respecting a smoking article, the person required to file a premarket notification shall provide an adequate summary of any health information related to the smoking article or state that such information will be made available upon request by any person.

(b) APPLICATION.—

(1) CONTENTS.—An application under this section shall contain—

(A) full reports of all information, published or known to, or which should reasonably be known to, the applicant, concerning investigations which have been made to show the health risks of such smoking article and whether such smoking article presents less risk than other smoking articles;

(B) a full statement of the components, ingredients, additives, and properties, and of the principle or principles of operation, of such smoking article;

(C) a full description of the methods used in, and the facilities and controls used for, the manufacture, processing, and, when relevant, packing and installation of, such smoking article;

(D) an identifying reference to any smoking article standard under section 111 which would be applicable to any aspect of such smoking article, and either adequate information to show that such aspect of such smoking article fully meets such smoking

article standard or adequate information to justify any deviation from such standard;

(E) such samples of such smoking article and of components thereof as the Administrator may reasonably require;

(F) specimens of the labeling proposed to be used for such smoking article; and

(G) such other information relevant to the subject matter of the application as the Administrator may require.

(2) REFERRAL TO TOBACCO PRODUCTS SCIENTIFIC ADVISORY COMMITTEE.—Upon receipt of an application meeting the requirements set forth in paragraph (1), the Administrator—

(A) may, on the Administrator's own initiative; or

(B) may, upon the request of an applicant, refer such application to the Tobacco Products Scientific Advisory Committee for reference and for submission (within such period as the Administrator may establish) of a report and recommendation respecting the application, together with all underlying data and the reasons or basis for the recommendation.

(c) ACTION ON APPLICATION.—

(1) DEADLINE.—As promptly as possible, but in no event later than 90 days after the receipt of an application under subsection (b), the Administrator, after considering the report and recommendation submitted under subsection (b)(2), shall—

(A) issue an order that the new product may be introduced or delivered for introduction into interstate commerce if the Administrator finds that none of the grounds specified in paragraph (2) of this subsection applies; or

(B) issue an order that the new product may not be introduced or delivered for introduction into interstate commerce if the Administrator finds (and sets forth the basis for such finding as part of or accompanying such denial) that 1 or more grounds for denial specified in paragraph (2) of this subsection apply.

(2) DENIAL OF APPLICATION.—The Administrator shall deny an application submitted under subsection (b) if, upon the basis of the information submitted to the Administrator as part of the application and any other information before the Administrator with respect to such smoking article, the Administrator finds that—

(A) there is a lack of a showing that permitting such smoking article to be marketed would be appropriate for the protection of the public health;

(B) the methods used in, or the facilities or controls used for, the manufacture, processing, or packing of such smoking article do not conform to the requirements of section 110(e);

(C) based on a fair evaluation of all material facts, the proposed labeling is false or misleading in any particular; or

(D) such smoking article is not shown to conform to a smoking article standard in effect under section 111, and there is a lack of adequate information to justify the deviation from such standard.

(3) DENIAL INFORMATION.—Any denial of an application shall, insofar as the Administrator determines to be practicable, be accompanied by a statement informing the applicant of the measures required to remove such application from deniable form (which measures may include further research by the applicant in accordance with 1 or more protocols prescribed by the Administrator).

(4) BASIS FOR FINDING.—For purposes of this section, the finding as to whether the commercial introduction of a smoking article for which an application has been submitted is appropriate for the protection of the public health shall be determined with respect to the risks and benefits to the users of the smoking article, and taking into account whether such commercial introduction is reasonably likely to increase the morbidly and mortality among individual tobacco users.

(d) WITHDRAWAL AND TEMPORARY SUSPENSION.—

(1) IN GENERAL.—The Administrator shall, upon obtaining, where appropriate, advice on scientific matters from the Tobacco Products Scientific Advisory Committee, and after due notice and opportunity for informal hearing for a smoking article for which an order was issued under subsection (c)(1)(A), issue an order withdrawing the order if the Administrator finds—

(A) that the continued marketing of such smoking article no longer is appropriate for the protection of the public health;

(B) that the application contained or was accompanied by an untrue statement of a material fact;

(C) that the applicant—

(i) has failed to establish a system for maintaining records, or has repeatedly or deliberately failed to maintain records or to make reports, required by an applicable regulation under section 113; or

(ii) has refused to permit access to, or copying or verification of, such records as required by section 110; or

(D) on the basis of new information before the Administrator with respect to such smoking article, evaluated together with the evidence before the Administrator when the application was reviewed, that the methods used in, or the facilities and controls used for, the manufacture, processing, packing, or installation of such smoking article do not conform with the requirements of section 110(e) and were not brought into conformity with such requirements within a reasonable time after receipt of written notice from the Administrator of nonconformity;

(E) on the basis of new information before the Administrator, evaluated together with the evidence before the Administrator when the application was reviewed, that the labeling of such smoking article, based on a fair evaluation of all material facts, is false or misleading in any particular and was not corrected within a reasonable time after receipt of written notice from the Administrator of such fact; or

(F) on the basis of new information before the Administrator, evaluated together with the evidence before the Administrator when such order was issued, that such smoking article is not shown to conform in all respects to a smoking article standard which is in effect under section 111, compliance with which was a condition to the issuance of an order relating to the application, and that there is a lack of adequate information to justify the deviation from such standard.

(2) APPEAL.—The holder of an application subject to an order issued under paragraph (1) withdrawing an order issued pursuant to subsection (c)(1)(A) may, by petition filed on or before the 30th day after the date upon which such holder receives notice of such withdrawal, obtain review thereof in accordance with section 116.

(3) TEMPORARY SUSPENSION.—If, after providing an opportunity for an informal hearing, the Administrator determines there is reasonable probability that the continuation of distribution of a smoking article under an order would cause serious, adverse health consequences or death, that is greater than ordinarily caused by smoking articles on the market, the Administrator shall by order temporarily suspend the authority of the manufacturer to market the product. If the Administrator issues such an order, the Administrator shall proceed expeditiously under paragraph (1) to withdraw such application.

(e) SERVICE OF ORDER.—An order issued by the Administrator under this section shall be served—

(1) in person by any officer or employee of the department designated by the Administrator; or

(2) by mailing the order by registered mail or certified mail addressed to the applicant at the applicant's last known address in the records of the Administrator.

(f) RECORDS.—

(1) ADDITIONAL INFORMATION.—In the case of any smoking article for which an order issued pursuant to subsection (c)(1)(A) for an application filed under subsection (b) is in effect, the applicant shall establish and maintain such records, and make such reports to the Administrator, as the Administrator may by regulation, or by order with respect to such application, prescribe on the basis of a finding that such records and reports are necessary in order to enable the Administrator to determine, or facilitate a determination of, whether there is or may be grounds for withdrawing or temporarily suspending such order.

(2) ACCESS TO RECORDS.—Each person required under this section to maintain records, and each person in charge of custody thereof, shall, upon request of an officer or employee designated by the Administrator, permit such officer or employee at all reasonable times to have access to and copy and verify such records.

(g) INVESTIGATIONAL SMOKING ARTICLE EXEMPTION FOR INVESTIGATIONAL USE.—The Administrator may exempt smoking articles intended for investigational use from the provisions of this Act under such conditions as the Administrator may by regulation prescribe.

SEC. 114. REDUCED RISK TOBACCO PRODUCTS.

(a) IN GENERAL.—No person may introduce or deliver for introduction into interstate commerce any reduced risk tobacco product unless an order issued pursuant to subsection (g) is effective with respect to such product.

(b) DEFINITIONS.—In this section:

(1) REDUCED RISK TOBACCO PRODUCT.—The term ''reduced risk tobacco product'' means any tobacco product that is sold or distributed for use to reduce harm or the risk of tobacco-related disease associated with commercially marketed tobacco products.

(2) SOLD OR DISTRIBUTED.—

(A) IN GENERAL.—With respect to a tobacco product, the term ''sold or distributed for use to reduce harm or the risk of tobacco-related disease associated with commercially marketed tobacco products'' means a tobacco product—

(i) the label, labeling, or advertising of which represents explicitly or implicitly that—

(I) the tobacco product presents a lower risk of tobacco-related disease or is less harmful than one or more other commercially marketed tobacco products;

(II) the tobacco product or its smoke contains a reduced level of a substance or presents a reduced exposure to a substance; or

(III) the tobacco product or its smoke does not contain or is free of a substance;

(ii) the label, labeling, or advertising of which uses the descriptors ''light'', ''mild'', ''low'', ''medium'', ''ultra light'', ''low tar'' or ''ultra low tar''; or

(iii) the tobacco product manufacturer of which has taken any action directed to consumers through the media or otherwise, other than by means of the tobacco product's label, labeling, or advertising, after the date of enactment of the Act, respecting the product that would be reasonably expected to result in consumers believing that the tobacco product or its smoke may present a lower

risk of disease or is less harmful than one or more commercially marketed tobacco products, or presents a reduced exposure to, or does not contain or is free of, a substance or substances.

(B) LIMITATION.—No tobacco product shall be considered to be ''sold or distributed for use to reduce harm or the risk of tobacco-related disease associated with commercially marketed tobacco products'', except as described in subparagraph (A).

(C) SMOKELESS TOBACCO PRODUCT.—No smokeless tobacco product shall be considered to be ''sold or distributed for use to reduce harm or the risk of tobacco-related disease associated with commercially marketed tobacco products''.

(3) EFFECTIVE DATE.—The provisions of paragraph (2)(A)(ii) shall take effect 12 months after the date of enactment of the Act.

(c) TOBACCO DEPENDENCE PRODUCTS.—A product that is intended to be used for the treatment of tobacco dependence, including smoking cessation, is not a reduced risk tobacco product under this section if it has been approved as a drug or device by the Center and is subject to the requirements of chapter V.

(d) FILING.—Any person may file with the Administrator an application for a reduced risk tobacco product. Such application shall include—

(1) a description of the proposed product and any proposed advertising and labeling;

(2) the conditions for using the product;

(3) the formulation of the product;

(4) sample product labels and labeling;

(5) all documents (including underlying scientific information) relating to research findings conducted, supported, or possessed by the tobacco product manufacturer relating to the effect of the product on tobacco-related diseases and health-related conditions, including information both favorable and unfavorable to the ability of the product to reduce risk or exposure and relating to human health;

(6) data and information on how consumers actually use the tobacco product; and

(7) such other information as the Administrator may require.

(e) PUBLIC AVAILABILITY.—The Administrator shall make the application described in subsection (d) publicly available (except matters in the application which are trade secrets or otherwise confidential, commercial information) and shall request comments by interested persons on the information contained in the application and on the label, labeling, and advertising accompanying such application.

(f) ADVISORY COMMITTEE.—

(1) IN GENERAL.—The Administrator shall refer to the Tobacco Products Scientific Advisory Committee any application submitted under this section.

(2) RECOMMENDATIONS.—Not later than 60 days after the date an application is referred to the Tobacco Products Scientific Advisory Committee under paragraph (1), the Advisory Committee shall report its recommendations on the application to the Administrator.

(g) MARKETING.—

(1) REDUCED RISK PRODUCTS.—Except as provided in paragraph (2), the Administrator shall, with respect to an application submitted under this section, issue an order that a reduced risk product may be commercially marketed only if the Administrator determines that the applicant has demonstrated that such product, as it is actually used by consumers, will—

(A) significantly reduce harm and the risk of tobacco-related disease to individual tobacco users; and

(B) is reasonably likely to result in measurable and substantial reductions in morbidity and mortality among individual tobacco users.

(2) SPECIAL RULE FOR CERTAIN PRODUCTS.—The Administrator may issue an order that a tobacco product may be introduced or delivered for introduction into interstate commerce, pursuant to an application under this section, with respect to a tobacco product that may not be commercially marketed under paragraph (1) if the Secretary makes the findings required under this paragraph and determines that the applicant has demonstrated that—

(A) such order would be appropriate to promote the public health; and

(B) the scientific evidence that is available without conducting long-term epidemiological studies demonstrates that a measurable and substantial reduction in morbidity or mortality among individual tobacco users is reasonably likely in subsequent studies.

(3) BASIS.—The determinations under paragraphs (1) and (2) shall be based on—

(A) the scientific evidence submitted by the applicant; and

(B) scientific evidence and other information that is made available to the Administrator.

(h) ADDITIONAL CONDITIONS FOR MARKETING.—

(1) REDUCED RISK PRODUCTS.—The Administrator shall require for the marketing of a product under this section that any advertising or labeling concerning reduced risk products enable the public to comprehend the information concerning reduced risk and to understand the relative significance of such information in the context of total health and in relation to all of the diseases and health-related conditions associated with the use of cigarettes and other tobacco products.

(2) COMPARATIVE CLAIMS.—The Administrator may require for the marketing of a product under this subsection that a claim comparing a tobacco product to other commercially marketed tobacco products shall compare the tobacco product to the known risk of cigarettes.

(i) POSTMARKET SURVEILLANCE AND STUDIES.—Under the guidance of the Scientific Advisory Committee, the Tobacco Harm Reduction Center shall engage in postmarket surveillance studies and other research as needed to ascertain the health impact of each of the major classes of tobacco and other nicotine containing products in the United States, ascertain the possible presence of unusual levels of harm from specific tobacco products, and determine the steps that should be taken to further reduce illness, death and other social harms from tobacco products.

(j) WITHDRAWAL OF AUTHORIZATION.—The Administrator, after an opportunity for an informal hearing, shall withdraw an order under subsection (g) if the Administrator determines that—

(1) the applicant, based on new information, can no longer make the demonstrations required under subsection (g), or the Administrator can no longer make the determinations required under subsection (g);

(2) the application failed to include material information or included any untrue statement of material fact;

(3) any explicit or implicit representation that the product reduces risk or exposure is no longer valid, including if—

(A) a tobacco product standard is established pursuant to section 111;

(B) an action is taken that affects the risks presented by other commercially marketed tobacco products that were compared to the product that is the subject of the application; or

(C) any postmarket surveillance or studies reveal that the order is no longer consistent with the protection of the public health;

(4) the applicant failed to conduct or submit the postmarket surveillance and studies required under subsection (g)(2)(C)(ii) or subsection (i); or

(5) the applicant failed to meet a condition imposed under subsection (h).

(k) CHAPTER IV OR V.—A product for which the Administrator has issued an order pursuant to subsection (g) shall not be subject to chapter IV or V of the Federal Food, Drug, and Cosmetic Act.

(l) IMPLEMENTING REGULATIONS OR GUIDANCE.—

(1) SCIENTIFIC EVIDENCE.—Not later than 2 years after the date of enactment of the Act, the Administrator shall issue regulations or guidance (or any combination thereof) on the scientific evidence required for assessment and ongoing review of reduced risk tobacco products. Such regulations or guidance shall—

(A) to the extent that adequate scientific evidence exists, establish minimum standards for scientific studies needed prior to issuing an order under subsection (g) to show a reasonable likelihood that a substantial reduction in morbidity or mortality among individual tobacco users occurs for products described in subsection (g)(1) or is reasonably likely for products described in subsection (g)(2);

(B) include validated biomarkers, intermediate clinical endpoints, and other feasible outcome measures, as appropriate;

(C) establish minimum standards for postmarket studies, that shall include regular and long-term assessments of health outcomes and mortality, intermediate clinical endpoints, consumer perception of harm reduction, and the impact on quitting behavior and new use of tobacco products, as appropriate;

(D) establish minimum standards for required postmarket surveillance, including ongoing assessments of consumer perception; and

(E) establish a reasonable timetable for the Administrator to review an application under this section.

(2) CONSULTATION.—The regulations or guidance issued under paragraph (1) may be developed in consultation with the Institute of Medicine, and with the input of other appropriate scientific and medical experts, on the design and conduct of such studies and surveillance.

(3) REVISION.—The regulations or guidance under paragraph (1) shall be revised on a regular basis as new scientific information becomes available.

(4) NEW TOBACCO PRODUCTS.—Not later than 2 years after the date of enactment of the Act, the Administrator shall issue a regulation or guidance that permits the filing of a single application for any tobacco product that is a new tobacco product under section 114 and which the applicant seeks to commercially market under this section.

SEC. 115. JUDICIAL REVIEW.

(a) RIGHT TO REVIEW.—

(1) IN GENERAL.—Not later than 60 days after—

(A) the promulgation of a regulation under section 111 establishing, amending, or revoking a tobacco product standard; or

(B) a denial of an application under section 114(c),

any person adversely affected by such regulation or denial may file a petition for judicial review of such regulation or denial with the United States Court of Appeals for the District of Columbia or for the circuit in which such person resides or has their principal place of business.

(2) REQUIREMENTS.—

(A) COPY OF PETITION.—A copy of the petition filed under paragraph (1) shall be transmitted by the clerk of the court involved to the Administrator.

(B) RECORD OF PROCEEDINGS.—On receipt of a petition under subparagraph (A), the Administrator shall file in the court in which such petition was filed—

(i) the record of the proceedings on which the regulation or order was based; and

(ii) a statement of the reasons for the issuance of such a regulation or order.

(C) DEFINITION OF RECORD.—In this section, the term ''record'' means—

(i) all notices and other matter published in the Federal Register with respect to the regulation or order reviewed;

(ii) all information submitted to the Administrator with respect to such regulation or order;

(iii) proceedings of any panel or advisory committee with respect to such regulation or order;

(iv) any hearing held with respect to such regulation or order; and

(v) any other information identified by the Administrator, in the administrative proceeding held with respect to such regulation or order, as being relevant to such regulation or order.

(b) STANDARD OF REVIEW.—Upon the filing of the petition under subsection (a) for judicial review of a regulation or order, the court shall have jurisdiction to review the regulation or order in accordance with chapter 7 of title 5, United States Code, and to grant appropriate relief, including interim relief, as provided for in such chapter. A regulation or denial described in subsection (a) shall be reviewed in accordance with section 706(2)(A) of title 5, United States Code.

(c) FINALITY OF JUDGMENT.—The judgment of the court affirming or setting aside, in whole or in part, any regulation or order shall be final, subject to review by the Supreme Court of the United States upon certiorari or certification, as provided in section 1254 of title 28, United States Code.

(d) OTHER REMEDIES.—The remedies provided for in this section shall be in addition to, and not in lieu of, any other remedies provided by law.

(e) REGULATIONS AND ORDERS MUST RECITE BASIS IN RECORD.—To facilitate judicial review, a regulation or order issued under section 110, 111, 112, 113, 114, or 119 shall contain a statement of the reasons for the issuance of such regulation or order in the record of the proceedings held in connection with its issuance.

SEC. 116. JURISDICTION OF AND COORDINATION WITH THE FEDERAL TRADE COMMISSION.

Except where expressly provided in this Act, nothing in this Act shall be construed as limiting or diminishing the authority of the Federal Trade Commission to enforce the laws under its jurisdiction with respect to the advertising, sale, or distribution of tobacco products.

SEC. 117. REGULATION REQUIREMENT.

(a) TESTING, REPORTING, AND DISCLOSURE.—Not later than 36 months after the date of enactment of the Act, the Administrator shall promulgate regulations under this Act that meet the requirements of subsection (b).

(b) CONTENTS OF RULES.—The regulations promulgated under subsection (a)—

(1) shall require annual testing and reporting of tobacco product constituents, ingredients, and additives, including smoke constituents, by brand style that the Administrator determines should be tested to protect the public health, provided that, for purposes of the testing requirements of this paragraph, tobacco products manufactured and sold by a single tobacco product manufacturer that are identical in all respects except the labels, packaging design, logo, trade dress, trademark, brand name, or any combination thereof, shall be considered as a single brand style; and

(2) may require that tobacco product manufacturers, packagers, or importers make disclosures relating to the results of the testing of tar and nicotine through labels or advertising.

(c) AUTHORITY.—The Administrator shall have the authority under this Act to conduct or to require the testing, reporting, or disclosure of tobacco product constituents, including smoke constituents.

(d) JOINT LABORATORY TESTING SERVICES.—The Administrator shall allow any 2 or more tobacco product manufacturers to join together to purchase laboratory testing services required by this section on a group basis in order to ensure that such manufacturers receive access to, and fair pricing of, such testing services.

(e) EXTENSIONS FOR LIMITED LABORATORY CAPACITY.—

(1) IN GENERAL.—The regulations promulgated under subsection (a) shall provide that a tobacco product manufacturer shall not be considered to be in violation of this section before the applicable deadline, if—

(A) the tobacco products of such manufacturer are in compliance with all other requirements of this Act; and

(B) the conditions described in paragraph (2) are met.

(2) CONDITIONS.—Notwithstanding the requirements of this section, the Administrator may delay the date by which a tobacco product manufacturer must be in compliance with the testing and reporting required by this section until such time as the testing is reported if, not later than 90 days before the deadline for reporting in accordance with this section, a tobacco product manufacturer provides evidence to the Administrator demonstrating that—

(A) the manufacturer has submitted the required products for testing to a laboratory and has done so sufficiently in advance of the deadline to create a reasonable expectation of completion by the deadline;

(B) the products currently are awaiting testing by the laboratory; and

(C) neither that laboratory nor any other laboratory is able to complete testing by the deadline at customary, nonexpedited testing fees.

(3) EXTENSION.—The Administrator, taking into account the laboratory testing capacity that is available to tobacco product manufacturers, shall review and verify the evidence submitted by a tobacco product manufacturer in accordance with paragraph (2). If the Administrator finds that the conditions described in such paragraph are met, the Administrator shall notify the tobacco product manufacturer that the manufacturer shall not be considered to be in violation of the testing and reporting requirements of this section until the testing is reported or until 1 year after the reporting deadline has passed, whichever occurs sooner. If, however, the Administrator has not made a finding before the reporting deadline, the manufacturer shall not be considered to be in violation of such requirements until the Administrator finds that the conditions described in paragraph (2) have not been met, or until 1 year after the reporting deadline, whichever occurs sooner.

(4) ADDITIONAL EXTENSION.—In addition to the time that may be provided under paragraph (3), the Administrator may provide further extensions of time, in increments of no more than 1 year, for required testing and reporting to occur if the Administrator determines, based on evidence properly and timely submitted by a tobacco product manufacturer in accordance with paragraph (2), that a lack of available laboratory capacity prevents the manufacturer from completing the required testing during the period described in paragraph (3).

(f) RULE OF CONSTRUCTION.—Nothing in subsection (d) or (e) shall be construed to authorize the extension of any deadline, or to otherwise affect any timeframe, under any provision of this Act other than this section.

SEC. 118. PRESERVATION OF STATE AND LOCAL AUTHORITY.

(a) IN GENERAL.—

(1) PRESERVATION.—Except as provided in paragraph (2)(A), nothing in this Act, or rules promulgated under this Act, shall be construed to limit the authority of a Federal agency (including the Armed Forces), a State or political subdivision of a State, or the government of an Indian tribe to enact, adopt, promulgate, and enforce any law, rule, regulation, or other measure with respect to tobacco products that is in addition to requirements established under this Act, including a law, rule, regulation, or other measure relating to or prohibiting the sale, distribution, possession, or use of tobacco products by individuals of any age, information reporting to the State. No provision of this Act shall limit or otherwise affect any State, Tribal, or local taxation of tobacco products.

(2) PREEMPTION OF CERTAIN STATE AND LOCAL REQUIREMENTS.—

(A) IN GENERAL.—No State or political subdivision of a State may establish or continue in effect with respect to a tobacco product any requirement which is different from, or in addition to, any requirement under the provisions of this Act relating to tobacco product standards, premarket review, adulteration, misbranding, labeling, registration, good manufacturing standards, or reduced risk tobacco products.

(B) EXCEPTION.—Subparagraph (A) does not apply to requirements relating to the sale, distribution, possession, information reporting to the State, use of, tobacco product by individuals of any age. Information disclosed to a State under subparagraph (A) that is exempt from disclosure under section 552(b)(4) of title 5, United States Code, shall be treated as a trade secret and confidential information by the State.

(b) RULE OF CONSTRUCTION REGARDING PRODUCT LIABILITY.—No provision of this Act relating to a tobacco product shall be construed to modify or otherwise affect any action or the liability of any person under the product liability law of any State.

SEC. 119. TOBACCO PRODUCTS SCIENTIFIC ADVISORY COMMITTEE.

(a) ESTABLISHMENT.—Not later than 6 months after the date of enactment of this Act, the Administrator shall establish a 19-member advisory committee, to be known as the Tobacco Products Scientific Advisory Committee (in this section referred to as the ''Advisory Committee'').

(b) MEMBERSHIP.—

(1) IN GENERAL.—

(A) MEMBERS.—The Administrator shall appoint as members of the Tobacco Harm Reduction Advisory Committee individuals who are technically qualified by training and experience in medicine, public health, medical ethics or other science or technology involving the means by which cigarettes and other tobacco products cause illness, death and other societal harms, and the steps that can be taken by government and the private sector to most rapidly and substantially reduce said illness, death and other societal harms. The committee shall be composed of—

(i) 10 individuals who are physicians, dentists, other scientists or other public health or healthcare professionals;

(ii) 4 individuals representing the general public;

(iii) 2 representatives of the interests of the tobacco manufacturing industry;

(iv) 1 representative of the interests of the small business tobacco manufacturing industry, which position may be filled on a rotating, sequential basis by representatives of different small business tobacco manufacturers based on areas of expertise relevant to the topics being considered by the Advisory Committee;

(v) 1 individual as a representative of the interests of the tobacco growers; and

(vi) 1 individual who is an expert in illicit trade of tobacco products.

(B) CONFLICTS OF INTEREST.—No members of the committee, other than members appointed pursuant to clauses (iv), (v), and (vi) of subparagraph (A) shall, during the member's tenure on the committee or for the 18-month period prior to becoming such a member, receive any salary, grants, or other payments or support from any business that manufactures, distributes, markets, or sells cigarettes or other tobacco products or government agency with any form of jurisdiction over tobacco products.

(2) LIMITATION.—The Administrator may not appoint to the Advisory Committee any individual who is in the regular full-time employ of the Tobacco Harm Reduction Center or any agency responsible for the enforcement of this Act. The Administrator may appoint Federal officials as ex officio members.

(3) CHAIRPERSON.—The Administrator shall designate 1 of the members appointed under clauses (i), (ii), and (iii) of paragraph (1)(A) to serve as chairperson.

(c) DUTIES.—The Tobacco Products Scientific Advisory Committee shall provide advice, information, and recommendations to the Administrator—

(1) as provided in this Act;

(2) on the implementation of prevention, cessation, and harm reduction policies;

(3) on implementation of policies and programs to fully inform consumers of the respective risks of tobacco products; and

(4) on its review of other safety, dependence, or health issues relating to tobacco products as requested by the Administrator.

(d) COMPENSATION; SUPPORT; FACA.—

(1) COMPENSATION AND TRAVEL.—Members of the Advisory Committee who are not officers or employees of the United States, while attending conferences or meetings of the committee or otherwise engaged in its business, shall be entitled to receive compensation at rates to be fixed by the Administrator, which may not exceed the daily equivalent of the rate in effect under the Senior Executive Schedule under section 5382 of title 5, United States Code, for each day (including travel time) they are so engaged; and while so serving away from their homes or regular places of business each member may be allowed travel expenses, including per diem in lieu of subsistence, as authorized by section 5703 of title 5, United States Code, for persons in the Government service employed intermittently.

(2) ADMINISTRATIVE SUPPORT.—The Administrator shall furnish the Advisory Committee clerical and other assistance.

(3) NONAPPLICATION OF FACA.—Section 14 of the Federal Advisory Committee Act does not apply to the Advisory Committee.

(e) PROCEEDINGS OF ADVISORY PANELS AND COMMITTEES.—The Advisory Committee shall make and maintain a transcript of any proceeding of the panel or committee. Each such panel and committee shall delete from any transcript made under this subsection information which is exempt from disclosure under section 552(b) of title 5, United States Code.

SEC. 120. DRUG PRODUCTS USED TO TREAT TOBACCO DEPENDENCE.

(a) REPORT ON INNOVATIVE PRODUCTS.—

(1) IN GENERAL.—Not later than 3 years after the date of enactment of this Act, the Administrator, after consultation with recognized scientific, medical, and public health experts (including both Federal agencies and nongovernmental entities, the Institute of Medicine of the National Academy of Sciences, and the Society for Research on Nicotine and Tobacco), shall submit to the Congress a report that examines how best to promote, and encourage the development and use by current tobacco users of innovative tobacco and nicotine products and treatments (including nicotine-based and non-nicotine-based products and treatments) to better achieve, in a manner that best protects and promotes the public health—

(A) total abstinence from tobacco use;

(B) reductions in consumption of tobacco; and

(C) reductions in the harm associated with continued tobacco use by moving current users to noncombustible tobacco products.

(2) RECOMMENDATIONS.—The report under paragraph (1) shall include the recommendations of the Administrator on how the Tobacco Harm and Reduction Center should coordinate and facilitate the exchange of information on such innovative products and treatments among relevant offices and centers within the Center and within the National Institutes of Health, the Centers for Disease Control and Prevention, and other relevant Federal and State agencies.

TITLE II—TOBACCO PRODUCTS WARNINGS; CONSTITUENT AND SMOKE CONSTITUENT DISCLOSURE

SEC. 201. CIGARETTE LABEL AND ADVERTISING WARNINGS.

(a) AMENDMENT.—Section 4 of the Federal Cigarette Labeling and Advertising Act (15 U.S.C. 1333) is amended to read as follows:

"SEC. 4. LABELING.

''(a) LABEL REQUIREMENTS.—

''(1) IN GENERAL.—It shall be unlawful for any person to manufacture, package, sell, offer to sell, distribute, or import for sale or distribution within the United States any cigarettes the package of which fails to bear, in accordance with the requirements of this section, one of the following labels:

''WARNING: Cigarettes are addictive.

''WARNING: Tobacco smoke can harm your children.

''WARNING: Cigarettes cause fatal lung disease.

''WARNING: Cigarettes cause cancer.

''WARNING: Cigarettes cause strokes and heart disease.

''WARNING: Smoking during pregnancy can harm your baby.

''WARNING: Smoking can kill you.

''WARNING: Tobacco smoke causes fatal lung disease in nonsmokers.

''WARNING: Quitting smoking now greatly reduces serious risks to your health.

''(2) PLACEMENT; TYPOGRAPHY; ETC.—Each label statement required by paragraph (1) shall be located in the lower portion of the front panel of the package, directly on the package underneath the cellophane or other clear wrapping. Each label statement shall comprise at least the bottom 25 percent of the front panel of the package. The word 'WARNING' shall appear in capital letters and all text shall be in conspicuous and legible 17-point type, unless the text of the label statement would occupy more than 70 percent of such area, in which case the text may be in a smaller conspicuous and legible type size, provided that at least 60 percent of such area is occupied by required text. The text shall be black on a white background, or white on a black background, in a manner that contrasts, by typography, layout, or color, with all other printed material on the package, in an alternating fashion under the plan submitted under subsection (c). The Secretary shall by regulation adjust the format and type size of the warnings required under this Act to include color graphics depicting the negative health consequences of smoking on the bottom portion of the front and rear panels.

''(3) DOES NOT APPLY TO FOREIGN DISTRIBUTION.—The provisions of this subsection do not apply to a tobacco product manufacturer or distributor of cigarettes which does not manufacture, package, or import cigarettes for sale or distribution within the United States.

''(4) APPLICABILITY TO RETAILERS.—A retailer of cigarettes shall not be in violation of this subsection for packaging that—

''(A) contains a warning label;

''(B) is supplied to the retailer by a license- or permit-holding smoking article manufacturer, importer, or distributor; and

''(C) is not altered by the retailer in a way that is material to the requirements of this subsection.

''(b) ADVERTISING REQUIREMENTS.—

''(1) IN GENERAL.—It shall be unlawful for any tobacco product manufacturer, importer, distributor, or retailer of cigarettes to advertise or cause to be advertised within the United States any cigarette unless its advertising bears, in accordance with the requirements of this section, one of the labels specified in subsection (a).

''(2) TYPOGRAPHY, ETC.—Each label statement required by subsection (a) in cigarette advertising shall comply with the standards set forth in this paragraph. For press and poster advertisements, each such statement and (where applicable) any required statement relating to tar, nicotine, or other constituent (including a smoke constituent) yield shall comprise at least 20 percent of the area of the advertisement and shall appear in a conspicuous and prominent format and location at the bottom of each advertisement within the trim area. The word 'WARNING' shall appear in capital letters, and each label statement shall appear in conspicuous and legible type. The text of the label statement shall be black if the background is white and white if the background is black, under the plan submitted under subsection (c). The label statements shall be enclosed by a rectangular border that is the same color as the letters of the statements and that is the width of the first downstroke of the capital 'W' of the word 'WARNING' in the label statements. The text of such label statements shall be in a typeface pro rata to the following requirements: 45-point type for a whole-page broadsheet newspaper advertisement; 39-point type for a half-page broadsheet newspaper advertisement; 39-point type for a whole-page tabloid newspaper advertisement; 27-point type for a half-page tabloid newspaper advertisement; 31.5-point type for a double page spread magazine or whole-page magazine advertisement; 22.5-point type for a 28 centimeter by 3 column advertisement; and 15-point type for a 20 centimeter by 2 column advertisement. The label statements shall be in English, except that—

''(A) in the case of an advertisement that appears in a newspaper, magazine, periodical, or other publication that is not in English, the statements shall appear in the predominant language of the publication; and

''(B) in the case of any other advertisement that is not in English, the statements shall

appear in the same language as that principally used in the advertisement.

''(3) MATCHBOOKS.—Notwithstanding paragraph (2), for matchbooks (defined as containing not more than 20 matches) customarily given away with the purchase of smokeless tobacco products, each label statement required by subsection (a) may be printed on the inside cover of the matchbook.

''(c) MARKETING REQUIREMENTS.—

''(1) RANDOM DISPLAY.—The label statements specified in subsection (a)(1) shall be randomly displayed in each 12-month period, in as equal a number of times as is possible on each brand of the product and be randomly distributed in all areas of the United States in which the product is marketed in accordance with a plan submitted by the smokeless tobacco product manufacturer, importer, distributor, or retailer and approved by the Secretary.

''(2) ROTATION.—The label statements specified in subsection (a)(1) shall be rotated quarterly in alternating sequence in advertisements for each brand of cigarettes in accordance with a plan submitted by the smokeless tobacco product manufacturer, importer, distributor, or retailer to, and approved by, the Secretary.

''(3) REVIEW.—The Secretary shall review each plan submitted under paragraph (2) and approve it if the plan—

''(A) will provide for the equal distribution and display on packaging and the rotation required in advertising under this subsection; and

''(B) assures that all of the labels required under this section will be displayed by the smokeless tobacco product manufacturer, importer, distributor, or retailer at the same time.

''(4) APPLICABILITY TO RETAILERS.—This subsection and subsection (b) apply to a retailer only if that retailer is responsible for or directs the label statements required under this section except that this paragraph shall not relieve a retailer of liability if the retailer displays, in a location open to the public, an advertisement that does not contain a warning label or has been altered by the retailer in a way that is material to the requirements of this subsection and subsection (b).''.

(b) EFFECTIVE DATE.—The amendment made by subsection (a) shall take effect 24 months after the date of enactment of this Act. Such effective date shall be with respect to the date of manufacture, provided that, in any case, beginning 30 days after such effective date, a manufacturer shall not introduce into the domestic commerce of the United States any product, irrespective of the date of manufacture, that is not in conformance with section 4 of the Federal Cigarette Labeling and Advertising Act (15 U.S.C. 1333), as amended by subsection (a).

SEC. 202. SMOKELESS TOBACCO LABELS AND ADVERTISING WARNINGS.

(a) AMENDMENT.—Section 3 of the Comprehensive Smokeless Tobacco Health Education Act of 1986 (15 U.S.C. 4402) is amended to read as follows:

''SEC. 3. SMOKELESS TOBACCO WARNING.

''(a) GENERAL RULE.—

''(1) It shall be unlawful for any person to manufacture, package, sell, offer to sell, distribute, or import for sale or distribution within the United States any smokeless tobacco product unless the product package bears, in accordance with the requirements of this Act, the following labels:

''WARNING: Smokeless tobacco is addictive.

''(2) Rotating warnings for all smokeless products shall consist of 'lower risk than cigarettes' and 'addictive' and the Secretary shall have the discretion to add warnings relating to mouth cancer, gum disease, and tooth loss to those smokeless products that have a demonstrated risk of such hazards.

''(3) The two main rotating warnings should be extended to the 'nicotine containing products.'

''(4) The label statements required by paragraph (1) shall be introduced by each smokeless tobacco product manufacturer, packager, importer, distributor, or retailer of smokeless tobacco products concurrently into the distribution chain of such products.

''(5) The provisions of this subsection do not apply to a smokeless tobacco product manufacturer or distributor of any smokeless tobacco product that does not manufacture, package, or import smokeless tobacco products for sale or distribution within the United States.

''(6) A retailer of smokeless tobacco products shall not be in violation of this subsection for packaging that—

''(A) contains a warning label;

''(B) is supplied to the retailer by a license- or permit-holding smokeless tobacco product manufacturer, importer, or distributor; and

''(C) is not altered by the retailer in a way that is material to the requirements of this subsection.

''(b) REQUIRED LABELS.—

''(1) It shall be unlawful for any smokeless tobacco product manufacturer, packager, importer, distributor, or retailer of smokeless tobacco products to advertise or cause to be advertised within the United States any smokeless tobacco product unless its advertising bears, in accordance with the requirements of this section, one of the labels specified in subsection (a).

''(2)(A) Each label statement required by subsection (a) in smokeless tobacco advertising shall comply with the standards set forth in this paragraph.

''(B) For press and poster advertisements, each such statement and (where applicable) any required statement relating to nicotine, or other constituent yield shall comprise at least 20 percent of the area of the advertisement.

''(C) The word 'WARNING' shall appear in capital letters, and each label statement shall appear in conspicuous and legible type.

''(D) The text of the label statement shall be black on a white background, or white on a black background, in an alternating fashion under the plan submitted under paragraph (3).

''(E) The label statements shall be enclosed by a rectangular border that is the same color as the letters of the statements and that is the width of the first downstroke of the capital 'W' of the word 'WARNING' in the label statements.

''(F) The text of such label statements shall be in a typeface pro rata to the following requirements: 45-point type for a whole-page broadsheet newspaper advertisement; 39-point type for a half-page broadsheet newspaper advertisement; 39-point type for a whole-page tabloid newspaper advertisement; 27-point type for a half-page tabloid newspaper advertisement; 31.5-point type for a double page spread magazine or whole-page magazine advertisement; 22.5-point type for a 28 centimeter by 3 column advertisement; and 15-point type for a 20 centimeter by 2 column advertisement.

''(G) The label statements shall be in English, except that—

''(i) in the case of an advertisement that appears in a newspaper, magazine, periodical, or other publication that is not in English, the statements shall appear in the predominant language of the publication; and

''(ii) in the case of any other advertisement that is not in English, the statements shall appear in the same language as that principally used in the advertisement.

''(3)(A) The label statements specified in subsection (a)(1) shall be randomly displayed in each 12-month period, in as equal a number of times as is possible on each brand of the product and be randomly distributed in all areas of the United States in which the product is marketed in accordance with a plan submitted by the smokeless tobacco product manufacturer, importer, distributor, or retailer and approved by the Secretary.

''(B) The label statements specified in subsection (a)(1) shall be rotated quarterly in alternating sequence in advertisements for each brand of smokeless tobacco product in accordance with a plan submitted by the smokeless tobacco product manufacturer, importer, distributor, or retailer to, and approved by, the Secretary.

''(C) The Secretary shall review each plan submitted under subparagraphs (A) and (B) and approve it if the plan—

''(i) will provide for the equal distribution and display on packaging and the rotation required in advertising under this subsection; and

''(ii) assures that all of the labels required under this section will be displayed by the smokeless tobacco product manufacturer, importer, distributor, or retailer at the same time.

''(D) This paragraph applies to a retailer only if that retailer is responsible for or directs the label statements under this section, unless the retailer displays, in a location open to the public, an advertisement that does not contain a warning label or has been altered by the retailer in a way that is material to the requirements of this subsection.

''(c) TELEVISION AND RADIO ADVERTISING.—It is unlawful to advertise smokeless tobacco on any medium of electronic communications subject to the jurisdiction of the Federal Communications Commission.''.

(b) EFFECTIVE DATE.—The amendment made by subsection (a) shall take effect 24 months after the date of enactment of this Act. Such effective date shall be with respect to the date of manufacture, provided that, in any case, beginning 30 days after such effective date, a manufacturer shall not introduce into the domestic commerce of the United States any product, irrespective of the date of manufacture, that is not in conformance with section 3 of the Comprehensive Smokeless Tobacco Health Education Act of 1986 (15 U.S.C. 4402), as amended by subsection (a).

TITLE III—PUBIC DISCLOSURES BY TOBACCO PRODUCTS MANUFACTURERS

SEC. 301. DISCLOSURES ON PACKAGES OF TOBACCO PRODUCTS.

(a) BACK FACE FOR REQUIRED DISCLOSURES.—For purposes of this section—

(1) the principal face of a package of a tobacco product is the face that has the largest surface area or, for faces with identical surface areas, any of the faces that have the largest surface area; a package shall not be characterized as having more than 2 principal faces;

(2) the front face shall be the principal face of the package;

(3) if the front and back faces are of different sizes in terms of area, then the larger face shall be the front face;

(4) the back face shall be the principal face of a package that is opposite the front face of the package;

(5) the bottom 50 percent of the back face of the package shall be allocated for required package disclosures in accordance with this section; and

(6) if a package of a tobacco product is cylindrical, a contiguous area constituting 30 percent of the total surface area of the cylinder shall be deemed the back face.

(b) REQUIRED INFORMATION ON BACK FACE.—Not later than 24 months after the effective date of this Act, the bottom 50 percent of the back face of a package of a tobacco product shall be available solely for disclosures required by or under this Act, the Federal Cigarette Labeling and Advertising Act, sections 1331–1340 of title 15, United States Code, and any other Federal statute. Such disclosures shall include—

(1) the printed name and address of the manufacturer, packer, or distributor, and any other identification associated with the manufacturer, packer, or distributor or with the tobacco product that the Administrator may require;

(2) a list of ingredients as required by subsection (e); and

(3) the appropriate tax registration number.

(c) PACKAGE DISCLOSURE OF INGREDIENTS.—Not later than 24 months after the effective date of this Act, the package of a tobacco product shall bear a list of the common or usual names of the ingredients present in the tobacco product in an amount greater than 0.1 percent of the total dry weight of the tobacco (including all ingredients), that shall comply with the following:

(1) Such listing of ingredients shall appear under, or be conspicuously accompanied by, the heading ''Tobacco and principal tobacco ingredients''.

(2) Tobacco may be listed as ''tobacco,'' and shall be the first listed ingredient.

(3) After tobacco, the ingredients shall be listed in descending order of predominance, by weight.

(4) Spices and natural and artificial flavors may be listed, respectively, as ''spices'' and ''natural and artificial flavors'' without naming each.

(5) Preservatives may be listed as ''preservatives'' without naming each.

(6) The disclosure of any ingredient in accordance with this section may, at the option of the tobacco product manufacturer, designate the functionality or purpose of that ingredient.

(7) The package say state ''Not for sale to minors''.

(8) In the case of a package of cigarettes, the package shall state that smokeless tobacco has significantly lower risks for disease and death than cigarettes.

SEC. 302. DISCLOSURES ON PACKAGES OF SMOKELESS TOBACCO.

(a) BACK FACE FOR REQUIRED DISCLOSURES.—For purposes of this section—

(1) the principal face of a package of smokeless tobacco is the face that has the largest surface area or, for faces with identical surface areas, any of the faces that have the largest surface area; a package shall not be characterized as having more than two principal faces;

(2) the front or top face shall be the principal face of the package;

(3) if the front or top and back or bottom faces are of different sizes in terms of area, then the larger face shall be the front or top face;

(4) the back or bottom face of the package shall be the principal face of a package that is opposite the front or top face of the package;

(5) beginning 24 months after the effective date of this Act, 50 percent of the back or bottom face of the package shall be allocated for required package disclosures in accordance with this section; and

(6) if the package is cylindrical, a contiguous area constituting 30 percent of the total surface area of the cylinder shall be deemed the back face.

(b) REQUIRED INFORMATION ON BACK OR BOTTOM FACE.—50 percent of the back or bottom face of a package of smokeless tobacco shall be available solely for disclosures required by or under this Act, the Comprehensive Smokeless Tobacco Health Education Act of 1986, sections 4401–4408 of title 15, United States Code, and any other Federal statute. Such disclosures shall include a list of ingredients as required by subsection (e).

(c) PACKAGE DISCLOSURE OF INGREDIENTS.—Commencing 24 months after the effective date of this Act, a package of smokeless tobacco shall bear a list of the common or usual names of the ingredients present in the smokeless tobacco in an amount greater than 0.1 percent of the total dry weight of the tobacco (including all ingredients).

(1) Such listing of ingredients shall appears under, or be conspicuously accompanied by, the heading ''Tobacco and principal tobacco ingredients''.

(2) Tobacco may be listed as ''tobacco,'' and shall be the first listed ingredient.

(3) After tobacco, the ingredients shall be listed in descending order of predominance, by weight.

(4) Spices and natural and artificial flavors may be listed, respectively, as ''spices'' and ''natural and artificial flavors'' without naming each.

(5) Preservatives may be listed as ''preservatives'' without naming each.

(6) The disclosure of any ingredient in accordance with this section may, at the option of the tobacco product manufacturer, designate the functionality or purpose of that ingredient.

(7) Not for sale to minors.

SEC. 303. PUBLIC DISCLOSURE OF INGREDIENTS.

(a) REGULATIONS.—Not later than 24 months after the effective date of this Act, the Administrator shall, by regulation, establish standards under which each tobacco product manufacturer shall disclose publicly, and update at least annually—

(1) a list of the ingredients it uses in each brand style it manufactures for commercial distribution domestically, as provided in subsection (b); and

(2) a composite list of all the ingredients it uses in any of the brand styles it manufactures for commercial distribution domestically, as provided in subsection (c).

(b) INGREDIENTS TO BE DISCLOSED AS TO EACH BRAND STYLE.—

(1) IN GENERAL.—With respect to the public disclosure required by subsection (a)(1), as to each brand style, the tobacco product manufacture shall disclose the common or usual name of each ingredient present in the brand style in an amount greater than 0.1 percent of the total dry weight of the tobacco (including all ingredients).

(2) REQUIREMENTS.—Disclosure under paragraph (1) shall comply with the following:

(A) Tobacco may be listed as ''tobacco,'' and shall be the first listed ingredient.

(B) After tobacco, the ingredients shall be listed in descending order of predominance, by weight.

(C) Spices and natural and artificial flavors may be listed, respectively, as ''spices'' and ''natural and artificial flavors'' without naming each.

(D) Preservatives may be listed as ''preservatives'' without naming each.

(E) The disclosure of any ingredient in accordance with this section may, at the option of the tobacco product manufacturer, designate the functionality or purpose of that ingredient.

(c) AGGREGATE DISCLOSURE OF INGREDIENTS.—

(1) IN GENERAL.—The public disclosure required of a tobacco product manufacturer by subsection (a)(2) shall consist of a single list of all ingredients used in any brand style a tobacco product manufacturer manufactures for commercial distribution domestically, without regard to the quantity used, and including, separately, each spice, each natural or artificial flavoring, and each preservative.

(2) LISTING.—The ingredients shall be listed by their respective common or usual names in descending order of predominance by the total weight used annually by the tobacco product manufacturer in manufacturing tobacco products for commercial distribution domestically.

(d) NO REQUIRED DISCLOSURE OF QUANTITIES.—The Administrator shall not require any public disclosure of quantitative information about any ingredient in a tobacco product.

(e) DISCLOSURE ON WEBSITE.—The public disclosures required by subsection (a) of this section may be by posting on an Internet-accessible website, or other location electronically accessible to the public, which is identified on all packages of a tobacco product manufacturer's tobacco products.

(f) TIMING OF INITIAL REQUIRED DISCLOSURES.—No disclosure pursuant to this section shall be required to commence until the regulations under subsection (a) have been in effect for not less than 1 year.

TITLE IV—PREVENTION OF ILLICIT TRADE IN TOBACCO PRODUCTS

SEC. 401. STUDY AND REPORT ON ILLICIT TRADE.

(a) The Administrator shall, after consultation with other relevant agencies including Customs and Tobacco Tax Bureau, conduct a study of trade in tobacco products that involves passage of tobacco products either between the States or from or to any other country across any border of the United States to—

(1) collect data on such trade in tobacco products, including illicit trade involving tobacco products, and make recommendations on the monitoring and enforcement of such trade;

(2) collect data on any advertising intended to be broadcast, transmitted, or distributed from or to the United States from or to another country and make recommendations on how to prevent or eliminate, and what technologies could help facilitate the elimination of, such advertising; and

(3) collect data on such trade in tobacco products by person that is not—

(A) a participating manufacturer (as that term is defined in section II(jj) of the Master Settlement Agreement of November 23, 1998, between certain of the States and certain tobacco product manufacturers); or

(B) an affiliate or subsidiary of a participating manufacturer.

(b) Not later than 18 months after the effective date of this Act, the Administrator shall submit to the Secretary, and committees of relevant jurisdiction in Congress, a report the recommendations of the study conducted under subsection (a).

SEC. 402. AMENDMENT TO SECTION 1926 OF THE PUBLIC HEALTH SERVICE ACT.

Section 1926 of the Public Health Service Act (42 U.S.C. § 300x–26) is amended by adding at the end thereof the following:

''(e)(1) Subject to paragraphs (2) and (3), for the first fiscal year after enactment and each subsequent fiscal year, the Secretary shall reduce, as provided in subsection (h), the amount of any grant under section 300x–21 of this title for any State that does not have in effect a statute with substantially the following provisions:

''''SEC. 1. DISTRIBUTION TO MINORS.

'''(a) No person shall distribute a tobacco product to an individual under 18 years of age or a different minimum age established under State law. A person who violates this subsection is liable for a civil money penalty of not less than $25 nor more than $125 for each violation of this subsection;

'''(b) The employer of an employee who has violated subsection (a) twice while in the

employ of such employer is liable for a civil money penalty of $125 for each subsequent violation by such employee.

''(c) It shall be a defense to a charge brought under subsection (a) that—

''(1) the defendant—

''(A) relied upon proof of age that appeared on its face to be valid in accordance with the Preventing Disease and Death from Tobacco Use Act;

''(B) had complied with the requirements of section 5 and, if applicable, section 7; or

''(C) relied upon a commercially available electronic age verification service to confirm that the person was an age-verified adult; or

''(2) the individual to whom the tobacco product was distributed was at the time of the distribution used in violation of subsection 7(b).

''SEC. 2. OUT-OF-PACKAGE DISTRIBUTION.

''It shall be unlawful for any person to distribute cigarettes or a smokeless tobacco product other than in an unopened package that complies in full with section 108 of the Preventing Disease and Death from Tobacco Use Act. A person who distributes a cigarette or a smokeless tobacco product in violation of this section is liable for a civil money penalty of not less than $25 nor more than $125 for each such violation.

''SEC. 3. SIGNAGE.

''It shall be unlawful for any person who sells tobacco products over-the-counter to fail to post conspicuously on the premises where such person sells tobacco products over-the-counter a sign communicating that—

''(1) the sale of tobacco products to individuals under 18 years of age or a different minimum age established under State law is prohibited by law;

''(2) the purchase of tobacco products by individuals under 18 years of age or a different minimum age established under State law is prohibited by law; and

''(3) proof of age may be demanded before tobacco products are sold.

A person who fails to post a sign that complies fully with this section is liable for a civil money penalty of not less than $25 nor more than $125.

''SEC. 4. NOTIFICATION OF EMPLOYEES.

''(a) Within 180 days of the effective date of the Preventing Disease and Death from Tobacco Use Act, every person engaged in the business of selling tobacco products at retail shall implement a program to notify each employee employed by that person who sells tobacco products at retail that—

''(1) the sale or other distribution of tobacco products to any individual under 18 years of age or a different minimum age established under State law, and the purchase, receipt, or possession of tobacco products in a place open to the public by any individual under 18 years of age or a different minimum age established under State law, is prohibited; and

''(2) out-of-package distribution of cigarettes and smokeless tobacco products is prohibited.

Any employer failing to provide the required notice to any employee shall be liable for a civil money penalty of not less than $25 nor more than $125 for each such violation.

''(b) It shall be a defense to a charge that an employer violated subsection (a) of this section that the employee acknowledged receipt, either in writing or by electronic means, prior to the alleged violation, of a statement in substantially the following form:

''I understand that State law prohibits the distribution of tobacco products to individuals under 18 years of age or a different minimum age established under State law and out-of-package distribution of cigarettes and smokeless tobacco products, and permits a defense based on evidence that a prospective purchaser's proof of age was reasonably relied upon and appeared on its face to be valid. I understand that if I sell, give, or voluntarily provide a tobacco product to an individual under 18 years of age or a different minimum age established under State law, I may be found responsible for a civil money penalty of not less than $25 nor more than $125 for each violation. I promise to comply with this law.'''

''(c) If an employer is charged with a violation of subsection (a) and the employer uses as a defense to such charge the defense provided by subsection (b), the employer shall be deemed to be liable for such violation if such employer pays the penalty imposed on the employee involved in such violation or in any way reimburses the employee for such penalty.

''SEC. 5. SELF-SERVICE DISPLAYS.

''(a) It shall be unlawful for any person who sells tobacco products over-the-counter at retail to maintain packages of such products in any location accessible to customers that is not under the control of a cashier or other employee during regular business hours. This subsection does not apply to any adult-only facility.

''(b) Any person who violates subsection (a) is liable for a civil money penalty of not less than $25 nor more than $125 for each such violation, except that no person shall be responsible for more than one violation per day at any one retail store.

''SEC. 6. DISTRIBUTION BY MAIL OR COURIER.

''(a) It shall be unlawful to distribute or sell tobacco products directly to consumers by mail or courier, unless the person receiving purchase requests for tobacco products takes reasonable action to prevent delivery to individuals who are not adults by—

''(1) requiring that addressees of the tobacco products be age-verified adults;

''(2) making good faith efforts to verify that such addressees have attained the minimum age for purchase of tobacco products established by the respective States wherein the addresses of the addressees are located; and

''(3) addressing the tobacco products delivered by mail or courier to a physical addresses and not to post office boxes.

''(b) Any person who violates subsection (a) is liable for a civil money penalty of not less than $25 nor more than $125 for each such violation.

''SEC. 7. RANDOM UNANNOUNCED INSPECTIONS; REPORTING; AND COMPLIANCE.

''(a) The State Police, or a local law enforcement authority duly designated by the State Police, or a public health authority shall enforce this Act in a manner that can reasonably be expected to reduce the extent to which tobacco products are distributed to individuals under 18 years of age or a different minimum age established under State law and shall conduct random, unannounced inspections in accordance with the procedures set forth in this Act and in regulations issued under section 1926 of the Federal Public Health Service Act (42 U.S.C. § 300x–26).

''(b) The State may engage an individual under 18 years of age or a different minimum age established under State law to test compliance with this Act, except that such an individual may be used to test compliance with this Act only if the testing is conducted under the following conditions:

''(1) Prior to use of any individual under 18 years of age or a different minimum age established under State law in a random, unannounced inspection, written consent shall be obtained from a parent, custodian, or guardian of such individual;

''(2) An individual under 18 years of age or a different minimum age established under State law shall act solely under the supervision and direction of the State Police or a local law enforcement authority, or public health authority duly designated by the State Police during a random, unannounced inspection;

''(3) An individual under 18 years of age or a different minimum age established under State law used in random, unannounced inspections shall not be used in any such inspection at a store in which such individual is a regular customer; and

''(4) If an individual under 18 years of age or a different minimum age established under State law participating in random, unannounced inspections is questioned during such an inspection about such individual's age, such individual shall state his or her actual age and shall present a true and correct proof of age if requested at any time during the inspection to present it.

''(c) Any person who uses any individual under 18 years of age or a different minimum age established under State law, other than as permitted by subsection (b), to test compliance with this Act, is liable for a civil money penalty of not less than $25 nor more than $125 for each such violation.

''(d) Civil money penalties collected for violations of this Act and fees collected under section 9 shall be used only to defray the costs of administration and enforcement of this Act.

''SEC. 8. LICENSURE.

''(a) Each person engaged in the over-the-counter distribution at retail of tobacco products shall hold a license issued under this section. A separate license shall be required for each place of business where tobacco products are distributed at retail. A license issued under this section is not assignable and is valid only for the person in whose name it is issued and for the place of business designated in the license.

''(b) The annual license fee is $25 for each place of business where tobacco products are distributed at retail.

''(c) Every application for a license, including renewal of a license, under this section shall be made upon a form provided by the appropriate State agency or department, and shall set forth the name under which the applicant transacts or intends to transact business, the location of the place of business for which the license is to be issued, the street address to which all notices relevant to the license are to be sent (in this Act referred to as ''notice address''), and any other identifying information that the appropriate State agency or department may require.

''(d) The appropriate State agency or department shall issue or renew a license or deny an application for a license or the renewal of a license within 30 days of receiving a properly completed application and the license fee. The appropriate State agency or department shall provide notice to an applicant of action on an application denying the issuance of a license or refusing to renew a license.

''(e) Every license issued by the appropriate State agency or department pursuant to this section shall be valid for 1 year from the date of issuance and shall be renewed upon application except as otherwise provided in this Act.

''(f) Upon notification of a change of address for a place of business for which a license has been issued, a license shall be reissued for the new address without the filing of a new application.

''(g) The appropriate State agency or department shall notify every person in the State who is engaged in the distribution at retail of tobacco products of the license requirements of this section and of the date by

which such person should have obtained a license.

''(h)(1) Except as provided in paragraph (2), any person who engages in the distribution at retail of tobacco products without a license required by this section is liable for a civil money penalty in an amount equal to (i) two times the applicable license fee, and (ii) $50 for each day that such distribution continues without a license.

''(2) Any person who engages in the distribution at retail of tobacco products after a license issued under this section has been suspended or revoked is liable for a civil money penalty of $100 per day for each day on which such distribution continues after the date such person received notice of such suspension or revocation.

''(i) No person shall engage in the distribution at retail of tobacco products on or after 180 days after the date of enactment this Act unless such person is authorized to do so by a license issued pursuant to this section or is an employee or agent of a person that has been issued such a license.

''SEC. 9. SUSPENSION, REVOCATION, DENIAL, AND NONRENEWAL OF LICENSES.

''(a) Upon a finding that a licensee has been determined by a court of competent jurisdiction to have violated this Act during the license term, the State shall notify the licensee in writing, served personally or by registered mail at the notice address, that any subsequent violation of this Act at the same place of business may result in an administrative action to suspend the license for a period determined by the specify the appropriate State agency or department.

''(b) Upon finding that a further violation by this Act has occurred involving the same place of business for which the license was issued and the licensee has been served notice once under subsection (a), the appropriate State agency or department may initiate an administrative action to suspend the license for a period to be determined by the appropriate State agency or department but not to exceed six months. If an administrative action to suspend a license is initiated, the appropriate State agency or department shall immediately notify the licensee in writing at the notice address of the initiation of the action and the reasons therefor and permit the licensee an opportunity, at least 30 days after written notice is served personally or by registered mail upon the licensee, to show why suspension of the license would be unwarranted or unjust.

''(c) The appropriate State agency or department may initiate an administrative action to revoke a license that previously has been suspended under subsection (b) if, after the suspension and during the one-year period for which the license was issued, the licensee committed a further violation of this Act, at the same place of business for which the license was issued. If an administrative action to revoke a license is initiated, the appropriate State agency or department shall immediately notify the licensee in writing at the notice address of the initiation of the action and the reasons therefor and permit the licensee an opportunity, at least 30 days after written notice is served personally or by registered mail upon the licensee, to show why revocation of the license would be unwarranted or unjust.

''(d) A person whose license has been suspended or revoked with respect to a place of business pursuant to this section shall pay a fee of $50 for the renewal or reissuance of the license at that same place of business, in addition to any applicable annual license fees.

''(e) Revocation of a license under subsection (c) with respect to a place of business shall not be grounds to deny an application by any person for a new license with respect to such place of business for more than 12 months subsequent to the date of such revocation. Revocation or suspension of a license with respect to a particular place of business shall not be grounds to deny an application for a new license, to refuse to renew a license, or to revoke or suspend an existing license at any other place of business.

''(f) A licensee may seek judicial review of an action of the appropriate State agency or department suspending, revoking, denying, or refusing to renew a license under this section by filing a complaint in a court of competent jurisdiction. Any such complaint shall be filed within 30 days after the date on which notice of the action is received by the licensee. The court shall review the evidence de novo.

''(g) The State shall not report any action suspending, revoking, denying, or refusing to renew a license under this section to the Federal Secretary of Health and Human Services, unless the opportunity for judicial review of the action pursuant to subsection (f), if any, has been exhausted or the time for seeking such judicial review has expired.

''SEC. 10. NO PRIVATE RIGHT OF ACTION.

''Nothing in this Act shall be construed to create a right of action by any private person for any violation of any provision of this Act.

''SEC. 11. JURISDICTION AND VENUE.

''Any action alleging a violation of this Act may be brought only in a court of general jurisdiction in the city or county where the violation is alleged to have occurred.

''SEC. 12. REPORT.

''The appropriate State agency or department shall prepare for submission annually to the Federal Secretary of Health and Human Services the report required by section 1926 of the Federal Public Health Service Act (42 U.S.C. 300x–26).''.

''(2) In the case of a State whose legislature does not convene a regular session in fiscal year 2007, and in the case of a State whose legislature does not convene a regular session in fiscal year 2008, the requirement described in subsection (e)(1) as a condition of a receipt of a grant under section 300x–21 of this title shall apply only for fiscal year 2009 and subsequent fiscal years.

''(3) Subsection (e)(1) shall not affect any State or local law that (A) was in effect on the date of introduction of the Federal Tobacco Act of 2007, and (B) covers the same subject matter as the law described in subsection (e)(1). Any State law that meets the conditions of this paragraph shall also be deemed to meet the requirement described in subsection (e)(1) as a condition of a receipt of a grant under section 300x–21 of this title, if such State law is at least as stringent as the law described in subsection (e)(1).

''(f)(1) For the first applicable fiscal year and for each subsequent fiscal year, a funding agreement for a grant under section 300x–21 of this title is a funding agreement under which the State involved will enforce the law described in subsection (e)(1) of this section in a manner that can reasonably be expected to reduce the extent to which tobacco products are available to individuals under the age of 18 or a different minimum age established under State law for the purchase of tobacco products.

''(2) For the first applicable fiscal year and for each subsequent fiscal year, a funding agreement for a grant under section 300x–21 of this title is a funding agreement under which the State involved will—

''(A) conduct random, unannounced inspections to ensure compliance with the law described in subsection (e)(1); and

''(B) annually submit to the Secretary a report describing—

''(i) the activities carried out by the State to enforce such law during the fiscal year preceding the fiscal year for which the State is seeking the grant;

''(ii) the extent of success the State has achieved in reducing the availability of tobacco products to individuals under 18 years of age or a different minimum age established under State law, including the results of the inspections conducted under subparagraph (A); and

''(iii) the strategies to be utilized by the State for enforcing such law during the fiscal year for which the grant is sought.

''(g) The law specified in subsection (e)(1) may be administered and enforced by a State using—

''(1) any amounts made available to the State through a grant under section 300x–21 of this title;

''(2) any amounts made available to the State under section 300w of this title;

''(3) any fees collected for licenses issued pursuant to the law described in subsection (e)(1);

''(4) any fines or penalties assessed for violations of the law specified in subsection (e)(1); or

''(5) any other funding source that the legislature of the State may prescribe by statute.

''(h) Before making a grant under section 300x–21 of this title to a State for the first applicable fiscal year or any subsequent fiscal year, the Secretary shall make a determination of whether the State has maintained compliance with subsections (e) and (f) of this section. If, after notice to the State and an opportunity for a hearing, the Secretary determines that the State is not in compliance with such subsections, the Secretary shall reduce the amount of the allotment under section 300x–21 of this title for the State for the fiscal year involved by an amount equal to—

''(1) In the case of the first applicable fiscal year, 10 percent of the amount determined under section 300x–33 for the State for the fiscal year;

''(2) In the case of the first fiscal year following such applicable fiscal year, 20 percent of the amount determined under section 300x–33 for the State for the fiscal year;

''(3) In the case of the second such fiscal year, 30 percent of the amount determined under section 300x–33 for the State for the fiscal year; and

''(4) In the case of the third such fiscal year or any subsequent fiscal year, 40 percent of the amount determined under section 300x–33 for the State for the fiscal year.

The Secretary shall not have authority or discretion to grant to any State a waiver of the terms and requirements of this subsection or subsection (e) or (f).

''(i) For the purposes of subsections (e) through (h) of this section the term 'first applicable fiscal year' means—

''(1) fiscal year 2009, in the case of any State described in subsection (e)(2) of this section; and

''(2) fiscal year 2008, in the case of any other State.

''(j) For purposes of subsections (e) through (h) of this section, references to section 300x–21 shall include any successor grant programs.''

''(k) As required by paragraph (1), and subject to paragraph (4), an Indian tribe shall satisfy the requirements of subsection (e)(1) of this section by enacting a law or ordinance with substantially the same provisions as the law described in subsection (e)(1).

''(1) An Indian tribe shall comply with subsection (e)(1) of this section within 180 days after the Administrator finds, in accordance with this paragraph, that—

''(A) the Indian tribe has a governing body carrying out substantial governmental powers and duties;

''(B) the functions to be exercised by the Indian tribe under this Act pertain to activities on trust land within the jurisdiction of the tribe; and

''(C) the Indian tribe is reasonably expected to be capable of carrying out the functions required under this section.

Within 2 years of the date of enactment of the Federal Tobacco Act of 2007, as to each Indian tribe in the United States, the Administrator shall make the findings contemplated by this paragraph or determine that such findings cannot be made, in accordance with the procedures specified in paragraph (4).

''(2) As to Indian tribes subject to subsection (e)(1) of this section, the Administrator shall promulgate regulations that—

''(A) provide whether and to what extent, if any, the law described in subsection (e)(1) may be modified as adopted by Indian tribes; and

''(B) ensure, to the extent possible, that each Indian tribe's retailer licensing program under subsection (e)(1) is no less stringent than the program of the State or States in which the Indian tribe is located.

''(3) If with respect to any Indian tribe the Administrator determines that compliance with the requirements of subsection (e)(1) is inappropriate or administratively infeasible, the Administrator shall specify other means for the Indian tribe to achieve the purposes of the law described in subsection (e)(1) with respect to persons who engage in the distribution at retail of tobacco products on tribal lands.

''(4) The findings and regulations promulgated under paragraphs (1) and (2) shall be promulgated in conformance with section 553 of title 5, United States Code, and shall comply with the following provisions:

''(A) In making findings as provided in paragraph (1), and in drafting and promulgating regulations as provided in paragraph (2) (including drafting and promulgating any revised regulations), the Administrator shall confer with, and allow for active participation by, representatives and members of Indian tribes, and tribal organizations.

''(B) In carrying out rulemaking processes under this subsection, the Administrator shall follow the guidance of subchapter III of chapter 5 of title 5, United States Code, commonly known as the 'Negotiated Rulemaking Act of 1990.'

''(C) The tribal participants in the negotiation process referred to in subparagraph (B) shall be nominated by and shall represent the groups described in this subsection and shall include tribal representatives from all geographic regions.

''(D) The negotiations conducted under this paragraph (4) shall be conducted in a timely manner.

''(E) If the Administrator determines that an extension of the deadlines under subsection (k)(1) of this section is appropriate, the Secretary may submit proposed legislation to Congress for the extension of such deadlines.

''(5) This subsection shall not affect any law or ordinance that (A) was in effect on tribal lands on the date of introduction of the Preventing Disease and Death from Tobacco Use Act, and (B) covers the same subject matter as the law described in subsection (e)(1). Any law or ordinance that meets the conditions of this paragraph shall also be deemed to meet the requirement described in subsection (k)(1), if such law or ordinance is at least as stringent as the law described in subsection (e)(1).

''(6) For purposes of this subsection—

''(A) 'Administrator' means the Administrator of the Tobacco Harm Reduction Center.

''(B) 'Indian tribe' has the meaning assigned that term in section 4(e) of the Indian Self Determination and Education Assistance Act, section 450b(e) of title 25, United States Code.

''(C) 'Tribal lands' means all lands within the exterior boundaries of any Indian reservation, all lands the title to which is held by the United States in trust for an Indian tribe, or lands the title to which is held by an Indian tribe subject to a restriction by the United States against alienation, and all dependent Indian communities.

''(D) 'tribal organization' has the meaning assigned that term in section 4(l) of the Indian Self Determination and Education Assistance Act, section 450b(l) of title 25, United States Code.''.

SEC. 403. ESTABLISHMENT OF RANKINGS.

(a) STANDARDS AND PROCEDURES FOR RANKINGS.—Within 24 months after the effective date of this Act, the Administrator shall, by regulation, after consultation with an Advisory Committee established for such purpose, establish the standards and procedures for promulgating rankings, comprehensible to consumers of tobacco products, of the following categories of tobacco products and also nicotine-containing products on the basis of the relative risks of serious or chronic tobacco-related diseases and adverse health conditions those categories of tobacco products and also nicotine-containing products respectively present—

(1) smoking articles, including—

(A) cigarettes;

(B) cigars;

(C) little cigars;

(D) loose tobacco for roll-your own tobacco products;

(E) loose tobacco for pipes, hookas, and other pipe-like devices; and

(F) other smoking articles;

(2) smokeless products, including—

(A) chewing tobacco;

(B) dry snuff;

(C) snus (a type of moist snuff);

(D) other forms of moist snuff; and

(E) dissolvable tobacco products (such as sticks, orbs, or lozenges); and

(3) nicotine containing non-tobacco or tobacco extract products, including—

(A) nicotine gum;

(B) nicotine patches;

(C) electronic cigarettes; and

(D) other forms of such products.

The Administrator shall not have authority or discretion to establish a relative-risk ranking of any category or subcategory of tobacco products or any category or subcategory of nicotine-containing products other than the ten categories specified in this subsection.

(b) CONSIDERATIONS IN PROMULGATING REGULATIONS.—In promulgating regulations under this section, the Administrator—

(1) shall take into account relevant epidemiologic studies and other relevant competent and reliable scientific evidence; and

(2) in assessing the risks of serious or chronic tobacco-related diseases and adverse health conditions presented by a particular category, shall consider the range of tobacco products or nicotine-containing products within the category, and shall give appropriate weight to the market shares of the respective products in the category.

(c) PROMULGATION OF RANKINGS OF CATEGORIES.—Once the initial regulations required by subsection (a) are in effect, the Administrator shall promptly, by order, after notice and an opportunity for comment, promulgate to the general public rankings of the categories of tobacco products and nicotine-containing products in accordance with those regulations. The Administrator shall promulgate the initial rankings of those categories of tobacco products and nicotine-containing products to the general public not later than January 1, 2010. Thereafter, on an annual basis, the Administrator shall, by order, promulgate to the general public updated rankings that are (1) in accordance with those regulations, and (2) reflect the scientific evidence available at the time of promulgation. The Administrator shall open and maintain an ongoing public docket for receipt of data and other information submitted by any person with respect to such annual promulgation of rankings.

TITLE V—ENFORCEMENT PROVISIONS

SEC. 501. PROHIBITED ACTS.

The following acts and the causing thereof are hereby prohibited—

(1) the introduction or delivery for introduction into interstate commerce of any tobacco product that is adulterated or misbranded;

(2) the adulteration or misbranding of any tobacco product in interstate commerce;

(3) the receipt in interstate commerce of any tobacco product that is known to be adulterated or misbranded, and the delivery or proffered delivery thereof for pay or otherwise;

(4) the failure to establish or maintain any record, or make any report or other submission, or to provide any notice required by or under this Act; or the refusal to permit access to, verification of, or copying of any record as required by this Act;

(5) the refusal to permit entry or inspection as authorized by this Act;

(6) the making to the Administrator of a statement, report, certification or other submission required by this Act, with knowledge that such statement, report, certification, or other submission is false in a material aspect;

(7) the manufacturing, shipping, receiving, storing, selling, distributing, possession, or use of any tobacco product with knowledge that it is an illicit tobacco product;

(8) the forging, simulating without proper permission, falsely representing, or without proper authority using any brand name;

(9) the using by any person to his or her own advantage, or revealing, other than to the Administrator or officers or employees of the Agency, or to the courts when relevant in any judicial proceeding under this Act, any information acquired under authority of this Act concerning any item which as a trade secret is entitled to protection; except that the foregoing does not authorize the withholding of information from either House of Congress or from, to the extent of matter within its jurisdiction, any committee or subcommittee of such committee or any joint committee of Congress or any subcommittee of such joint committee;

(10) the alteration, mutilation, destruction, obliteration, or removal of the whole or any part of the labeling of, or the doing of any other act with respect to, a tobacco product, if such act is done while such tobacco product is held for sale (whether or not the first sale) after shipment in interstate commerce, and results in such tobacco product being adulterated or misbranded;

(11) the importation of any tobacco product that is adulterated, misbranded, or otherwise not in compliance with this Act; and

(12) the commission of any act prohibited by section 201 of this Act.

SEC. 502. INJUNCTION PROCEEDINGS.

(a) The district courts of the United States shall have jurisdiction, for cause shown, to restrain violations of this Act, except for violations of section 701(k).

(b) In case of an alleged violation of an injunction or restraining order issued under this section, which also constitutes a violation of this Act, trial shall be by the court, or upon demand of the defendant, by a jury.

SEC. 503. PENALTIES.

(a) CRIMINAL PENALTIES.—Any person who willfully violates a provision of section 501 of this Act shall be imprisoned for not more than one year or fined not more than $25,000, or both.

(b) CIVIL PENALTIES FOR VIOLATION OF SECTION 803.—

(1) Any person who knowingly distributes or sells, other than through retail sale or retail offer for sale, any cigarette brand style in violation of section 803(a)—

(A) for a first offense shall be liable for a civil penalty not to exceed $10,000 for each distribution or sale, or

(B) for a second offense shall be liable for a civil penalty not to exceed $25,000 for each distribution or sale,

except that the penalty imposed against any person with respect to violations during any 30-day period shall not exceed $100,000.

(2) Any retailer who knowingly distributes, sells or offers for sale any cigarette brand style in violation of section 803(a) shall—

(A) for a first offense for each sale or offer for sale of cigarettes, if the total number of packages of cigarettes sold or offered for sale—

(i) does not exceed 50 packages of cigarettes, be liable for a civil penalty not to exceed $500 for each sale or offer for sale, and

(ii) exceeds 50 packages of cigarettes, be liable for a civil penalty not to exceed $1,000 for each sale or offer for sale;

(B) for each subsequent offense for each sale or offer for sale of cigarettes, if the total number of cigarettes sold or offered for sale—

(i) does not exceed 50 packages of cigarettes, be liable for a civil penalty not to exceed $2,000 for each sale or offer for sale, and

(ii) exceeds 50 packages of cigarettes, be liable for a civil penalty not to exceed $5,000 for each sale or offer for sale;

except that the penalty imposed against any person during any 30-day period shall not exceed $25,000.

SEC. 504. SEIZURE.

(a) ARTICLES SUBJECT TO SEIZURE.—

(1) Any tobacco product that is adulterated or misbranded when introduced into or while in interstate commerce or while held for sale (whether or not the first sale) after shipment in interstate commerce, or which may not, under the provisions of this Act, be introduced into interstate commerce, shall be liable to be proceeded against while in interstate commerce, or at any time thereafter, on libel of information and condemned in any district court of the United States within the jurisdiction of which the tobacco product is found. No libel for condemnation shall be instituted under this Act for any alleged misbranding if there is pending in any court a libel for condemnation proceeding under this Act based upon the same alleged misbranding, and not more than one such proceeding shall be instituted if no such proceeding is so pending, except that such limitations shall not apply—

(A) when such misbranding has been the basis of a prior judgment in favor of the United States, in a criminal, injunction, or libel for condemnation proceeding under this Act, or

(B) when the Administrator has probable cause to believe from facts found, without hearing, by the Administrator or any officer or employee of the Agency that the misbranded tobacco product is dangerous to health beyond the inherent danger to health posed by tobacco, or that the labeling of the misbranded tobacco product is fraudulent, or would be in a material respect misleading to the injury or damage of the purchaser or consumer. In any case where the number of libel for condemnation proceedings is limited as above provided, the proceeding pending or instituted shall, on application of the claimant, seasonably made, be removed for trial to any district agreed upon by stipulation between the parties, or, in case of failure to so stipulate within a reasonable time, the claimant may apply to the court of the district in which the seizure has been made, and such court (after giving the United States attorney for such district reasonable notice and opportunity to be heard) shall by order, unless good cause to the contrary is shown, specify a district of reasonable proximity to the claimant's principal place of business, to which the case shall be removed for trial.

(2) The following shall be liable to be proceeded against at any time on libel of information and condemned in any district court of the United States within the jurisdiction of which they are found—

(A) any tobacco product that is an illicit tobacco product;

(B) any container of an illicit tobacco product;

(C) any equipment or thing used in making an illicit tobacco product; and

(D) any adulterated or misbranded tobacco product.

(3)(A) Except as provided in subparagraph (B), no libel for condemnation may be instituted under paragraph (1) or (2) against any tobacco product which—

(i) is misbranded under this Act because of its advertising, and

(ii) is being held for sale to the ultimate consumer in an establishment other than an establishment owned or operated by a manufacturer, packer, or distributor of the tobacco product.

(B) A libel for condemnation may be instituted under paragraph (1) or (2) against a tobacco product described in subparagraph (A) if the tobacco product's advertising which resulted in the tobacco product being misbranded was disseminated in the establishment in which the tobacco product is being held for sale to the ultimate consumer—

(i) such advertising was disseminated by, or under the direction of, the owner or operator of such establishment, or

(ii) all or part of the cost of such advertising was paid by such owner or operator.

(b) PROCEDURES.—The tobacco product, equipment, or other thing proceeded against shall be liable to seizure by process pursuant to the libel, and the procedure in cases under this section shall conform, as nearly as may be, to the procedure in admiralty; except that on demand of either party any issue of fact joined in any such case shall be tried by jury. When libel for condemnation proceedings under this section, involving the same claimant and the same issues of adulteration or misbranding, are pending in two or more jurisdictions, such pending proceedings, upon application of the claimant seasonably made to the court of one such jurisdiction, shall be consolidated for trial by order of such court, and tried in (1) any district selected by the claimant where one of such proceedings is pending; or (2) a district agreed upon by stipulation between the parties. If no order for consolidation is so made within a reasonable time, the claimant may apply to the court of one such jurisdiction and such court (after giving the United States attorney for such district reasonable notice and opportunity to be heard) shall by order, unless good cause to the contrary is shown, specify a district of reasonable proximity to the claimant's principal place of business, in which all such pending proceedings shall be consolidated for trial and tried. Such order of consolidation shall not apply so as to require the removal of any case the date for trial of which has been fixed. The court granting such order shall give prompt notification thereof to the other courts having jurisdiction of the cases covered thereby.

(c) SAMPLES AND ANALYSES.—The court at any time after seizure up to a reasonable time before trial shall by order allow any party to a condemnation proceeding, the party's attorney or agent, to obtain a representative sample of the article seized and a true copy of the analysis, if any, on which the proceeding is based and the identifying marks or numbers, if any, of the packages from which the samples analyzed were obtained.

(d) DISPOSITION OF CONDEMNED TOBACCO PRODUCTS.—(1) Any tobacco product condemned under this section shall, after entry of the decree, be disposed of by destruction or sale as the court may, in accordance with the provisions of this section, direct; and the proceeds thereof, if sold, less the legal costs and charges, shall be paid into the Treasury of the United States; but such tobacco product shall not be sold under such decree contrary to the provisions of this Act or the laws of the jurisdiction in which sold. After entry of the decree and upon the payment of the costs of such proceedings and the execution of a good and sufficient bond conditioned that such article shall not be sold or disposed of contrary to the provisions of this Act or the laws of any State in which sold, the court may by order direct that such tobacco product be delivered to the owner thereof to be destroyed or brought into compliance with the provisions of this Act, under the supervision of an officer or employee duly designated by the Administrator; and the expenses of such supervision shall be paid by the person obtaining release of the tobacco product under bond. If the tobacco product was imported into the United States and the person seeking its release establishes (A) that the adulteration, misbranding, or violation did not occur after the tobacco product was imported, and (B) that the person seeking the release of the tobacco product had no cause for believing that it was adulterated, misbranded, or in violation before it was released from customs custody, the court may permit the tobacco product to be delivered to the owner for exportation under section 709 in lieu of destruction upon a showing by the owner that there is a reasonable certainty that the tobacco product will not be re-imported into the United States.

(2) The provisions of paragraph (1) of this subsection shall, to the extent deemed appropriate by the court, apply to any equipment or other thing which is not otherwise within the scope of such paragraph and which is referred to in paragraph (2) of subsection (a).

(3) Whenever in any proceeding under this section, involving paragraph (2) of subsection (a), the condemnation of any equipment or thing (other than a tobacco product) is decreed, the court shall allow the claim of any claimant, to the extent of such claimant's interest, for remission or mitigation of such forfeiture if such claimant proves to the satisfaction of the court (A) that such claimant has not caused the equipment or thing to be within one of the categories referred to in such paragraph (2) and has no interest in any tobacco product referred to therein, (B) that such claimant has an interest in such equipment or other thing as owner or lienor or otherwise, acquired by such claimant in good faith, and (C) that such claimant at no time had any knowledge or reason to believe that such equipment or other thing was being or would be used in, or to facilitate, the violation of laws of the United States relating to any illicit tobacco product.

(e) COSTS AND FEES.—When a decree of condemnation is entered against the tobacco product or other article, court costs and fees, and storage and other proper expenses shall

be awarded against the person, if any, intervening as claimant of the tobacco product or other article.

(f) REMOVAL FOR TRIAL.—In the case of removal for trial of any case as provided by subsection (a) or (b)—

(1) The clerk of the court from which removal is made shall promptly transmit to the court in which the case is to be tried all records in the case necessary in order that such court may exercise jurisdiction.

(2) The court to which such case was removed shall have the powers and be subject to the duties, for purposes of such case, which the court from which removal was made would have had, or to which such court would have been subject, if such case had not been removed.

(g) ADMINISTRATIVE DETENTION OF TOBACCO PRODUCTS.—

(1) DETENTION AUTHORITY.—

(A) IN GENERAL.—An officer or qualified employee of the Agency may order the detention, in accordance with this subsection, of any tobacco product that is found during an inspection, examination, or investigation under this Act conducted by such officer or qualified employee, if the officer or qualified employee has credible evidence or information indicating that such article presents a threat of serious adverse health consequences beyond those normally inherent in the use of tobacco products.

(B) ADMINISTRATOR'S APPROVAL.—A tobacco product or component thereof may be ordered detained under subparagraph (A) if, but only if, the Administrator or an official designated by the Administrator approves the order. An official may not be so designated unless the official is an officer with supervisory responsibility for the inspection, examination, or investigation that led to the order.

(2) PERIOD OF DETENTION.—A tobacco product may be detained under paragraph (1) for a reasonable period, not to exceed 20 days, unless a greater period, not to exceed 30 days, is necessary, to institute an action under subsection (a) or section 702.

(3) SECURITY OF DETAINED TOBACCO PRODUCT.—An order under paragraph (1) may require that the tobacco product to be detained be labeled or marked as detained, and shall require that the tobacco product be maintained in or removed to a secure facility, as appropriate. A tobacco product subject to such an order shall not be transferred by any person from the place at which the tobacco product is ordered detained, or from the place to which the tobacco product is so removed, as the case may be, until released by the Administrator or until the expiration of the detention period applicable under such order, whichever occurs first. This subsection may not be construed as authorizing the delivery of the tobacco product pursuant to the execution of a bond while the tobacco product is subject to the order, and section 709 does not authorize the delivery of the tobacco product pursuant to the execution of a bond while the article is subject to the order.

(4) APPEAL OF DETENTION ORDER.—

(A) IN GENERAL.—With respect to a tobacco product ordered detained under paragraph (1), any person who would be entitled to be a claimant of such tobacco product if the tobacco product were seized under subsection (a) may appeal the order to the Administrator. Within five days after such an appeal is filed, the Administrator, after providing opportunity for an informal hearing, shall confirm or terminate the order involved, and such confirmation by the Administrator shall be considered a final agency action for purposes of section 702 of title 5, United States Code. If during such five-day period the Administrator fails to provide such an opportunity, or to confirm or terminate such order, the order is deemed to be terminated.

(B) EFFECT OF INSTITUTING COURT ACTION.—The process under subparagraph (A) for the appeal of an order under paragraph (1) terminates if the Administrator institutes an action under subsection (a) or section 702 regarding the tobacco product involved.

SEC. 505. REPORT OF MINOR VIOLATIONS.

Nothing in this Act shall be construed as requiring the Administrator to report for prosecution, or for institution of libel or injunction proceedings, minor violations of this Act whenever the Administrator believes that the public interest will be adequately served by a suitable written notice or warning.

SEC. 506. INSPECTION.

(a) AUTHORITY TO INSPECT.—The Administrator shall have the power to inspect the premises of a tobacco product manufacturer for purposes of determining compliance with this Act, or the regulations promulgated under it. Officers of the Agency designated by the Administrator, upon presenting appropriate credentials and a written notice to the person in charge of the premises, are authorized to enter, at reasonable times, without a search warrant, any factory, warehouse, or other establishment in which tobacco products are manufactured, processed, packaged, or held for domestic distribution. Any such inspection shall be conducted within reasonable limits and in a reasonable manner, and shall be limited to examining only those things, including but not limited to records, relevant to determining whether violations of this Act, or regulations under it, have occurred. No inspection authorized by this section shall extend to financial data, sales data other than shipment data, pricing data, personnel data (other than data as to qualifications of technical and professional personnel performing functions subject to this Act), or research data. A separate notice shall be given for each such inspection, but a notice shall not be required for each entry made during the period covered by the inspection. Each such inspection shall be commenced and completed with reasonable promptness.

(b) REPORT OF OBSERVATIONS.—Before leaving the premises, the officer of the Agency who has supervised or conducted the inspection shall give to the person in charge of the premises a report in writing setting forth any conditions or practices that appear to manifest a violation of this Act, or the regulations under it.

(c) SAMPLES.—If the officer has obtained any sample in the course of inspection, prior to leaving the premises that officer shall give to the person in charge of the premises a receipt describing the samples obtained. As to each sample obtained, the officer shall furnish promptly to the person in charge of the premises a copy of the sample and of any analysis made upon the sample.

SEC. 507. EFFECT OF COMPLIANCE.

Compliance with the provisions of this Act and the regulations promulgated under it shall constitute a complete defense to any civil action, including but not limited to any products liability action, that seeks to recover damages, whether compensatory or punitive, based upon an alleged defect in the labeling or advertising of any tobacco product distributed for sale domestically.

SEC. 508. IMPORTS.

(a) IMPORTS; LIST OF REGISTERED FOREIGN ESTABLISHMENTS; SAMPLES FROM UNREGISTERED FOREIGN ESTABLISHMENTS; EXAMINATION AND REFUSAL OF ADMISSION.—The Secretary of Homeland Security shall deliver to the Administrator, upon request by the Administrator, samples of tobacco products that are being imported or offered for import into the United States, giving notice thereof to the owner or consignee, who may appear before the Administrator and have the right to introduce testimony. The Administrator shall furnish to the Secretary of Homeland Security a list of establishments registered pursuant to subsection (d) of section 109 of this Act, and shall request that, if any tobacco products manufactured, prepared, or processed in an establishment not so registered are imported or offered for import into the United States, samples of such tobacco products be delivered to the Administrator, with notice of such delivery to the owner or consignee, who may appear before the Administrator and have the right to introduce testimony. If it appears from the examination of such samples or otherwise that (1) such tobacco product is forbidden or restricted in sale in the country in which it was produced or from which it was exported, or (2) such tobacco product is adulterated, misbranded, or otherwise in violation of this Act, then such tobacco product shall be refused admission, except as provided in subsection (b) of this section. The Secretary of Homeland Security shall cause the destruction of any such tobacco product refused admission unless such tobacco product is exported, under regulations prescribed by the Secretary of Homeland Security, within ninety days of the date of notice of such refusal or within such additional time as may be permitted pursuant to such regulations.

(b) DISPOSITION OF REFUSED TOBACCO PRODUCTS.—Pending decision as to the admission of a tobacco product being imported or offered for import, the Secretary of Homeland Security may authorize delivery of such tobacco product to the owner or consignee upon the execution by such consignee of a good and sufficient bond providing for the payment of such liquidated damages in the event of default as may be required pursuant to regulations of the Secretary of Homeland Security. If it appears to the Administrator that a tobacco product included within the provisions of clause (3) of subsection (a) of this section can, by relabeling or other action, be brought into compliance with this Act or rendered other than a tobacco product, final determination as to admission of such tobacco product may be deferred and, upon filing of timely written application by the owner or consignee and the execution by such consignee of a bond as provided in the preceding provisions of this subsection, the Administrator may, in accordance with regulations, authorize the applicant to perform such relabeling or other action specified in such authorization (including destruction or export of rejected tobacco products or portions thereof, as may be specified in the Administrator's authorization). All such relabeling or other action pursuant to such authorization shall in accordance with regulations be under the supervision of an officer or employee of the Agency designated by the Administrator, or an officer or employee of the Department of Homeland Security designated by the Secretary of Homeland Security.

(c) CHARGES CONCERNING REFUSED TOBACCO PRODUCTS.—All expenses (including travel, per diem or subsistence, and salaries of officers or employees of the United States) in connection with the destruction provided for in subsection (a) of this section and the supervision of the relabeling or other action authorized under the provisions of subsection (b) of this section, the amount of such expenses to be determined in accordance with regulations, and all expenses in connection with the storage, cartage, or labor with respect to any tobacco product refused admission under subsection (a) of this section, shall be paid by the owner or consignee and, in default of such payment, shall

constitute a lien against any future importations made by such owner or consignee.

SEC. 509. TOBACCO PRODUCTS FOR EXPORT.

(a) EXEMPTION FOR TOBACCO PRODUCTS EXPORTED.—Except as provided in subsection (b), a tobacco product intended for export shall be exempt from this Act if—

(1) it is not in conflict with the laws of the country to which it is intended fore export, as shown by either (A) a document issued by the government of that country or (B) a document provided by a person knowledgeable with respect to the relevant laws of that country and qualified by training and experience to opine on whether the tobacco product is or is not in conflict with such laws;

(2) it is labeled on the outside of the shipping package that it is intended for export; and

(3) the particular units of tobacco product intended for export have not been sold or offered for sale in domestic commerce.

(b) PRODUCTS FOR U.S. ARMED FORCES OVERSEAS.—A tobacco product intended for export shall not be exempt from this Act if it is intended for sale or distribution to members or units of the Armed Forces of the United States located outside of the United States.

(c) This Act shall not apply to a person that manufactures and/or distributes tobacco products solely for export under subsection (a), except to the extent such tobacco products are subject to subsection (b).

TITLE VI—MISCELLANEOUS PROVISIONS

SEC. 601. USE OF PAYMENTS UNDER THE MASTER SETTLEMENT AGREEMENT AND INDIVIDUAL STATE SETTLEMENT AGREEMENTS.

(a) REDUCTION OF GRANT AMOUNTS.—(1) For fiscal year 2010 and each subsequent fiscal year, the Secretary shall reduce, as provided in subsection (b), the amount of any grant under section 1921 of the Public Health Service Act (42 U.S.C. § 300x–21) for any State that spends on tobacco control programs from the funds received by such State pursuant to the Master Settlement Agreement, the Florida Settlement Agreement, the Minnesota Settlement Agreement, the Mississippi Memorandum of Understanding, or the Texas Settlement Agreement, as applicable, less than 20 percent of the amounts received by that State from settlement payments.

(2) In the case of a State whose legislature does not convene a regular session in fiscal year 2009 or 2010, and in the case of a State whose legislature does not convene a regular session in fiscal year 2010, the requirement described in subsection (a)(1) as a condition of receipt of a grant under section 1921 of the Public Health Service Act shall apply only for fiscal year 2009 and subsequent fiscal years.

(b) DETERMINATION OF STATE SPENDING.—Before making a grant under section 1921 of the Public Health Service Act, section 300x–21 of title 42, United States Code, to a State for the first applicable fiscal year or any subsequent fiscal year, the Secretary shall make a determination of whether, during the immediately preceding fiscal year, the State has spent on tobacco control programs, from the funds received by such State pursuant to the Master Settlement Agreement, the Florida Settlement Agreement, the Minnesota Settlement Agreement, the Mississippi Memorandum of Understanding, or the Texas Settlement Agreement, as applicable, at least the amount referenced in (a)(1). If, after notice to the State and an opportunity for a hearing, the Secretary determines that the State has spent less than such amount, the Secretary shall reduce the amount of the allotment under section 300x–21 of title 42, United States Code, for the State for the fiscal year involved by an amount equal to—

(1) in the case of the first applicable fiscal year, 10 percent of the amount determined under section 300x–33 of title 42, United States Code, for the State for the fiscal year;

(2) in the case of the first fiscal year following such applicable fiscal year, 20 percent of the amount determined under section 300x–33 of title 42, United States Code, for the State for the fiscal year;

(3) in the case of the second such fiscal year, 30 percent of the amount determined under section 300x–33 of title 42, United States Code, for the State for the fiscal year; and

(4) in the case of the third such fiscal year or any subsequent fiscal year, 40 percent of the amount determined under section 300x–33 of title 42, United States Code, for the State for the fiscal year.

The Secretary shall not have authority or discretion to grant to any State a waiver of the terms and requirements of this subsection or subsection (a).

(c) DEFINITIONS.—For the purposes of this section—

(1) The term ''first applicable fiscal year'' means—

(A) fiscal year 2011, in the case of any State described in subsection (a)(2) of this section; and

(B) fiscal year 2010, in the case of any other State.

(2) The term ''Florida Settlement Agreement'' means the Settlement Agreement, together with the exhibits thereto, entered into on August 25, 1997, between the State of Florida and signatory tobacco product manufacturers, as specified therein.

(3) The term ''Master Settlement Agreement'' means the Master Settlement Agreement, together with the exhibits thereto, entered into on November 23, 1998, between the signatory States and signatory tobacco product manufacturers, as specified therein.

(4) The term ''Minnesota Settlement Agreement'' means the Settlement Agreement, together with the exhibits thereto, entered into on May 8, 1998, between the State of Minnesota and signatory tobacco product manufacturers, as specified therein.

(5) The term ''Mississippi Memorandum of Understanding'' means the Memorandum of Understanding, together with the exhibits thereto and Settlement Agreement contemplated therein, entered into on July 2, 1997, between the State of Mississippi and signatory tobacco product manufacturers, as specified therein.

(6) The term ''Secretary'' means the Secretary of Health and Human Services.

(7) The term ''Texas Settlement Agreement'' means the Settlement Agreement, together with the exhibits thereto, entered into on January 16, 1998, between the State of Texas and signatory tobacco product manufacturers, as specified therein.

SEC. 602. INSPECTION BY THE ALCOHOL AND TOBACCO TAX TRADE BUREAU OF RECORDS OF CERTAIN CIGARETTE AND SMOKELESS TOBACCO SELLERS.

(a) IN GENERAL.—Any officer of the Bureau of the Alcohol and Tobacco Tax Trade Bureau may, during normal business hours, enter the premises of any person described in subsection (b) for the purposes of inspecting—

(1) any records or information required to be maintained by such person under the provisions of law referred to in subsection (d); or

(2) any cigarettes or smokeless tobacco kept or stored by such person at such premises.

(b) COVERED PERSONS.—Subsection (a) applies to any person who engages in a delivery sale, and who ships, sells, distributes, or receives any quantity in excess of 10,000 cigarettes, or any quantity in excess of 500 single-unit consumer-sized cans or packages of smokeless tobacco, within a single month.

(c) RELIEF.—

(1) IN GENERAL.—The district courts of the United States shall have the authority in a civil action under this subsection to compel inspections authorized by subsection (a).

(2) VIOLATIONS.—Whoever violates subsection (a) or an order issued pursuant to paragraph (1) shall be subject to a civil penalty in an amount not to exceed $10,000 for each violation.

(d) COVERED PROVISIONS OF LAW.—The provisions of law referred to in this subsection are—

(1) the Act of October 19, 1949 (15 U.S.C. 375; commonly referred to as the ''Jenkins Act'');

(2) chapter 114 of title 18, United States Code; and

(3) this Act.

(e) DELIVERY SALE DEFINED.—In this section, the term ''delivery sale'' has the meaning given that term in 2343(e) of title 18, United States Code, as amended by this Act.

SEC. 603. SEVERABILITY.

If any provision of this Act, the amendments made by this Act, or the application of any provision of this Act to any person or circumstance is held to be invalid, the remainder of this Act, the amendments made by this Act, and the application of the provisions of this Act to any other person or circumstance shall not be affected, and shall continue to be enforced to the fullest extent possible.

TITLE VII—TOBACCO GROWER PROTECTION

SEC. 701. TOBACCO GROWER PROTECTION.

No provision in this Act shall allow the Administrator or any other person to require changes to traditional farming practices, including standard cultivation practices, curing processes, seed composition, tobacco type, fertilization, soil, record keeping, or any other requirement affecting farming practices.

TITLE VIII—RESTRICTIONS ON YOUTH ACCESS TO TOBACCO PRODUCTS AND EXPOSURE OF YOUTHS TO TOBACCO PRODUCT MARKETING AND ADVERTISING

SEC. 801. PROHIBITIONS ON YOUTH TARGETING.

Effective beginning on the date that is 18 months after the effective date of this Act, no person shall engage in any of the following activities or practices in the advertising, promotion, or marketing of any tobacco product:

(1) The use, or causing the use, of any cartoon in the advertising, promoting, packaging, or labeling of any tobacco product.

(2) The use, or causing the use, of any human image in the advertising, promoting, packaging, or labeling of any tobacco product, except for the following:

(A) The use, or continued use, in advertising, promoting, marketing, packaging, or labeling of any human image appearing on a tobacco product package before December 31, 2009.

(B) The use, or continued use, of a human image in the advertising, promoting, or marketing of a tobacco product, if conducted solely in an adult-only facility or facilities.

(C) The use, or continued use, of a human image in a tobacco product communication means directed solely to persons that the tobacco product manufacturer has a good-faith belief are age-verified adults.

(3) The advertising of tobacco products in any magazine or newspaper intended for distribution to the general public.

(4) The engaging in any brand name sponsorship in the United States, other than a brand name sponsorship occurring solely in an adult-only facility or facilities.

(5) The engaging in any brand name sponsorship of any event in the United States in which any paid participants or contestants are youths.

(6) The sponsoring of any athletic event between opposing teams in any football, basketball, baseball, soccer, or hockey league.

(7)(A) The securing of a right, by agreement, to name any stadium or arena located within the United States with a brand name; or

(B) otherwise causing a stadium or arena located within the United States to be named with a brand name.

(8) The securing of a right by agreement pursuant to which payment is made or other consideration is provided to use a brand name in association with any football, basketball, baseball, soccer, or hockey league, or any team involved in any such league.

(9) The use of, or causing the use of, by agreement requiring the payment of money or other consideration, a brand name with any nationally recognized or nationally established trade name or brand designation of any non-tobacco item or service, or any nationally recognized or nationally established sports team, entertainment group or individual celebrity for purposes of advertising, except for an agreement between or among persons that enter into such agreement for the sole purpose of avoiding infringement claims.

(10) The license, express authorization, or otherwise causing of any person to use or advertise within the United States any brand name in a manner that—

(A) does not pertain to a tobacco product; or

(B) causes that person to use the brand name to advertise, promote, package or label, distribute, or sell any product or service that is not a tobacco product.

(11) The marketing, distribution, offering, selling, licensing, or authorizing of, or the causing to be marketed, distributed, offered, sold, licensed, or authorized, any apparel or other merchandise (other than a tobacco product) bearing a brand name, except—

(A) apparel or other merchandise that is used by individuals representing a tobacco product manufacturer within an adult-only facility and that is not distributed, by sale or otherwise, to any member of the general public;

(B) apparel or merchandise provided to an adult employee of a tobacco product manufacturer for use by such employee;

(C) items or materials used to hold or display tobacco products at retail;

(D) items or materials the sole function of which is to advertise tobacco products;

(E) written or electronic publications;

(F) coupons or other items used by adults solely in connection with the purchase of tobacco products;

(G) that the composition, structure, form, or appearance of any tobacco product, package, label, or labeling shall not be affected by the prohibitions of this paragraph; and

(H) that no person shall be required to retrieve, collect or otherwise recover any item or material that was marketed, distributed, offered, sold, licensed, or caused to be marketed, distributed, offered, sold, or licensed by such person.

(12) The distribution, or causing the distribution, of any free sample domestically, except in an adult-only facility or facilities to individuals who are age-verified adults.

(13) The making of, or causing to be made, any payment or the payment of, or causing to be paid, any other consideration to any other person to use, display, make reference to, or use as a prop in any performance medium (for the purposes of this paragraph, the terms ''performance medium'' and ''performance media'' mean any motion picture, television show, theatrical production or other live performance, live or recorded performance of music, commercial film or video, or video game), any tobacco product, tobacco product package, advertisement for a tobacco product, or any other item bearing a brand name; except for the following:

(A) Performance media for which the audience or viewers are within one or more adult-only facilities, if such performance media are not audible or visible to persons outside such adult-only facility or facilities.

(B) Performance media not intended to be heard or viewed by the general public.

(C) Instructional performance media that concern tobacco products and their use, and that are intended to be heard or viewed only by, or provided only to, age-verified adults.

(D) Performance media used in tobacco product communications to age-verified adults.

(14) Engaging in outdoor advertising or transit advertisements of tobacco products within the United States, except for the following:

(A) Advertising that is within an adult-only facility.

(B) The use of outdoor advertising for purposes of identification of an adult-only facility, to the extent that such outdoor advertising is placed at the site, premises, or location of the adult-only facility.

(C) The use of outdoor advertising in identifying a brand name sponsorship at an adult-only facility, if such outdoor advertising—

(i) is placed at the site, premises, or location of the adult-only facility where such brand name sponsorship will occur no more than 30 days before the start of the initial sponsored event; and

(ii) is removed within 10 days after the end of the last sponsored event.

(15) The distribution or sale domestically of any package or other container of cigarettes containing fewer than 20 cigarettes.

(16) The advertising of tobacco products on any broadcast, cable, or satellite transmission to a television or radio receiver, or other medium of electronic communication subject to the jurisdiction of the Federal Communications Commission, except electronic communications—

(A) contained on log-in or home pages containing no tobacco product advertising other than brand name identification;

(B) in an adult-only facility or facilities; or

(C) through the Internet or other individual user-accessible electronic communication means, including websites accessible using the Internet, if the advertiser takes reasonable action to restrict access to individuals who are adults by—

(i) requiring individuals accessing such electronic communications to be age-verified adults, and

(ii) making good faith efforts to verify that such individuals are adults.

(17) The distribution or sale of tobacco products directly to consumers by mail or courier, unless the person receiving purchase requests for tobacco products takes reasonable action to prevent delivery to individuals who are not adults by—

(A) requiring that the addressees of the tobacco products be age-verified adults;

(B) making good faith efforts to verify that such addressees are adults; and

(C) addressing the tobacco products delivered by mail, courier or common carrier to a physical address and not a post office box.

(18) The providing of any gift of a non-tobacco product, except matches, in connection with the purchase of a tobacco product.

(19) The engaging in the sponsorship or promotion, or causing the sponsorship or promotion, of any consumer sweepstakes, contest, drawing, or similar activity resulting in the award of a prize in connection with advertising.

(20) The offering, promoting, conducting, or authorizing, or causing to be offered, promoted, conducted, or authorized, any consumer sweepstakes, drawing, contest, or other activity resulting in the award of a prize, based on redemption of a proof-of-purchase, coupon, or other item awarded as a result of the purchase or use of a tobacco product.

(21) The making of, or causing to be made, any payment or the payment of, or causing to be paid, any other consideration, to any other person with regard to the display or placement of any cigarettes, or any advertising for cigarettes, in any retail establishment that is not an adult-only facility.

TITLE IX—USER FEES

SEC. 901. USER FEES.

(a) ASSESSMENT OF USER FEES.—The Administrator shall assess an annual user fee for each fiscal year beginning in fiscal year 2010, in an amount calculated in accordance with this section, upon each tobacco product manufacturer (including each importer) that is subject to this Act.

(b) USE OF FEE.—The Administrator shall utilize an amount equal to the amount of user fees collected under this section in each fiscal year to pay for the costs of the activities of the Tobacco Regulatory Agency related to the regulation of tobacco products under this Act.

(c) AMOUNT OF FEE.—

(1) IN GENERAL.—Except as provided in paragraph (2), the total amount of user fees assessed for each fiscal year pursuant to this section shall be sufficient, and shall not exceed the amount necessary, to pay for the costs of the activities described in subsection (b) for that fiscal year.

(2) TOTAL.—The total assessment under this section—

(A) for fiscal years 2010, 2011, and 2012 shall be $100,000,000; and

(B) for each subsequent fiscal year, shall not exceed the limit on the assessment imposed during the previous fiscal year, as adjusted by the Administrator (after notice, published in the Federal Register) to be determined on the basis of both inflationary increases and guidance from the Scientific Advisory Committee—

(3) NOTIFICATION.—The Administrator shall notify each tobacco product manufacturer subject to this section of the amount of the annual assessment imposed on such tobacco product manufacturer under subsection (d). Such notifications shall occur not later than the July 31 prior to the beginning of the fiscal year for which such assessment is made, and payments of all assessments shall be made not later than 60 days after each such notification. Such notification shall contain a complete list of the assessments imposed on tobacco product manufacturers for that fiscal year.

(d) LIABILITY OF TOBACCO PRODUCT MANUFACTURERS FOR USER FEES.—

(1) IN GENERAL.—The user fee to be paid by each tobacco product manufacturer shall be determined in each fiscal year by multiplying—

(A) such tobacco product manufacturer's market share of tobacco products, as determined under regulations issued pursuant to subsection (e); by

(B) the total user fee assessment for such fiscal year, as determined under subsection (c).

(2) LIMITATION.—Except as provided in paragraph (3), no tobacco product manufacturer shall be required to pay a percentage of a total annual user fee for all tobacco product manufacturers that exceeds the market share of such manufacturer.

(3) FAILURE TO PAY.—If—

(A) a tobacco product manufacturer fails to pay its user fee share in full by the due date;

(B) the Administrator, after diligent inquiry, concludes that such manufacturer is unlikely to pay its user fee share in full by the time such payment will be needed by the Administrator; and

(C) the Administrator and the Department of Justice make diligent efforts to obtain payment in full from such tobacco product manufacturer;

the Administrator may re-allocate the unpaid amount owed by that tobacco product manufacturer to the other tobacco product manufacturers on the basis of their respective market shares. If the Administrator takes such action, the Administrator shall set a reasonable time, not less than 60 days from the date of the notice of the amount due, for payment of that amount. If and to the extent that the Administrator ultimately receives from that tobacco product manufacturer or any successor to such tobacco product manufacturer any payment in respect of the previously unpaid obligation, the Administrator shall credit such payment to the tobacco product manufacturers that paid portions of the re-allocated amount, in proportion to their respective payments of such amount.

(e) REGULATIONS.—Not later than 12 months after the date of enactment of this Act, the Administrator shall, by regulation, establish a system for determining the market shares of tobacco products for each tobacco product manufacturer subject to this section. In promulgating regulations under this subsection, the Administrator shall—

(1) take into account the differences between categories and subcategories of tobacco products in terms of sales, manner of unit packaging, and any other factors relevant to the calculation of market share for a tobacco product manufacturer;

(2) take into account that different tobacco product manufacturers rely to varying degrees on the sales of different categories and subcategories of tobacco products; and

(3) provide that the market share of tobacco products for each tobacco product manufacturer shall be recalculated on an annual basis.

SA 1247. Mr. DODD proposed an amendment to the bill H.R. 1256, to protect the public health by providing the Food and Drug Administration with certain authority to regulate tobacco products, to amend title 5, United States Code, to make certain modifications in the Thrift Savings Plan, the Civil Service Retirement System, and the Federal Employees' Retirement System, and for other purposes; as follows:

Strike all after the enacting clause and insert the following:

DIVISION A—FAMILY SMOKING PREVENTION AND TOBACCO CONTROL ACT

SECTION 1. SHORT TITLE; TABLE OF CONTENTS.

(a) SHORT TITLE.—This division may be cited as the ''Family Smoking Prevention and Tobacco Control Act''.

(b) TABLE OF CONTENTS.—The table of contents of this division is as follows:

SEC. 2. FINDINGS.

The Congress finds the following:

(1) The use of tobacco products by the Nation's children is a pediatric disease of considerable proportions that results in new generations of tobacco-dependent children and adults.

(2) A consensus exists within the scientific and medical communities that tobacco products are inherently dangerous and cause cancer, heart disease, and other serious adverse health effects.

(3) Nicotine is an addictive drug.

(4) Virtually all new users of tobacco products are under the minimum legal age to purchase such products.

(5) Tobacco advertising and marketing contribute significantly to the use of nicotine-containing tobacco products by adolescents.

(6) Because past efforts to restrict advertising and marketing of tobacco products have failed adequately to curb tobacco use by adolescents, comprehensive restrictions on the sale, promotion, and distribution of such products are needed.

(7) Federal and State governments have lacked the legal and regulatory authority and resources they need to address comprehensively the public health and societal problems caused by the use of tobacco products.

(8) Federal and State public health officials, the public health community, and the public at large recognize that the tobacco industry should be subject to ongoing oversight.

(9) Under article I, section 8 of the Constitution, the Congress is vested with the responsibility for regulating interstate commerce and commerce with Indian tribes.

(10) The sale, distribution, marketing, advertising, and use of tobacco products are activities in and substantially affecting interstate commerce because they are sold, marketed, advertised, and distributed in interstate commerce on a nationwide basis, and have a substantial effect on the Nation's economy.

(11) The sale, distribution, marketing, advertising, and use of such products substantially affect interstate commerce through the health care and other costs attributable to the use of tobacco products.

(12) It is in the public interest for Congress to enact legislation that provides the Food and Drug Administration with the authority to regulate tobacco products and the advertising and promotion of such products. The benefits to the American people from enacting such legislation would be significant in human and economic terms.

(13) Tobacco use is the foremost preventable cause of premature death in America. It causes over 400,000 deaths in the United States each year, and approximately 8,600,000 Americans have chronic illnesses related to smoking.

(14) Reducing the use of tobacco by minors by 50 percent would prevent well over 10,000,000 of today's children from becoming regular, daily smokers, saving over 3,000,000 of them from premature death due to tobacco-induced disease. Such a reduction in youth smoking would also result in approximately $75,000,000,000 in savings attributable to reduced health care costs.

(15) Advertising, marketing, and promotion of tobacco products have been especially directed to attract young persons to use tobacco products, and these efforts have resulted in increased use of such products by youth. Past efforts to oversee these activities have not been successful in adequately preventing such increased use.

(16) In 2005, the cigarette manufacturers spent more than $13,000,000,000 to attract new users, retain current users, increase current consumption, and generate favorable long-term attitudes toward smoking and tobacco use.

(17) Tobacco product advertising often misleadingly portrays the use of tobacco as socially acceptable and healthful to minors.

(18) Tobacco product advertising is regularly seen by persons under the age of 18, and persons under the age of 18 are regularly exposed to tobacco product promotional efforts.

(19) Through advertisements during and sponsorship of sporting events, tobacco has become strongly associated with sports and has become portrayed as an integral part of sports and the healthy lifestyle associated with rigorous sporting activity.

(20) Children are exposed to substantial and unavoidable tobacco advertising that leads to favorable beliefs about tobacco use, plays a role in leading young people to overestimate the prevalence of tobacco use, and increases the number of young people who begin to use tobacco.

(21) The use of tobacco products in motion pictures and other mass media glamorizes its use for young people and encourages them to use tobacco products.

(22) Tobacco advertising expands the size of the tobacco market by increasing consumption of tobacco products including tobacco use by young people.

(23) Children are more influenced by tobacco marketing than adults: more than 80 percent of youth smoke three heavily marketed brands, while only 54 percent of adults, 26 and older, smoke these same brands.

(24) Tobacco company documents indicate that young people are an important and often crucial segment of the tobacco market. Children, who tend to be more price sensitive than adults, are influenced by advertising and promotion practices that result in drastically reduced cigarette prices.

(25) Comprehensive advertising restrictions will have a positive effect on the smoking rates of young people.

(26) Restrictions on advertising are necessary to prevent unrestricted tobacco advertising from undermining legislation prohibiting access to young people and providing for education about tobacco use.

(27) International experience shows that advertising regulations that are stringent and comprehensive have a greater impact on overall tobacco use and young people's use than weaker or less comprehensive ones.

(28) Text only requirements, although not as stringent as a ban, will help reduce underage use of tobacco products while preserving the informational function of advertising.

(29) It is in the public interest for Congress to adopt legislation to address the public health crisis created by actions of the tobacco industry.

(30) The final regulations promulgated by the Secretary of Health and Human Services in the August 28, 1996, issue of the Federal Register (61 Fed. Reg. 44615–44618) for inclusion as part 897 of title 21, Code of Federal Regulations, are consistent with the first amendment to the United States Constitution and with the standards set forth in the amendments made by this subtitle for the regulation of tobacco products by the Food and Drug Administration, and the restriction on the sale and distribution of, including access to and the advertising and promotion of, tobacco products contained in such regulations are substantially related to accomplishing the public health goals of this division.

(31) The regulations described in paragraph (30) will directly and materially advance the Federal Government's substantial interest in reducing the number of children and adolescents who use cigarettes and smokeless tobacco and in preventing the life-threatening health consequences associated with tobacco use. An overwhelming majority of Americans who use tobacco products begin using such products while they are minors and become addicted to the nicotine in those products before reaching the age of 18. Tobacco advertising and promotion play a crucial role in the decision of these minors to begin using tobacco products. Less restrictive and less comprehensive approaches have not and will not be effective in reducing the problems addressed by such regulations. The reasonable restrictions on the advertising and promotion of tobacco products contained in such regulations will lead to a significant decrease in the number of minors using and becoming addicted to those products.

(32) The regulations described in paragraph (30) impose no more extensive restrictions on communication by tobacco manufacturers and sellers than are necessary to reduce the number of children and adolescents who use cigarettes and smokeless tobacco and to prevent the life-threatening health consequences associated with tobacco use. Such regulations are narrowly tailored to restrict those advertising and promotional practices which are most likely to be seen or heard by youth and most likely to entice them into tobacco use, while affording tobacco manufacturers and sellers ample opportunity to convey information about their products to adult consumers.

(33) Tobacco dependence is a chronic disease, one that typically requires repeated interventions to achieve long-term or permanent abstinence.

(34) Because the only known safe alternative to smoking is cessation, interventions should target all smokers to help them quit completely.

(35) Tobacco products have been used to facilitate and finance criminal activities both domestically and internationally. Illicit trade of tobacco products has been linked to organized crime and terrorist groups.

(36) It is essential that the Food and Drug Administration review products sold or distributed for use to reduce risks or exposures associated with tobacco products and that it be empowered to review any advertising and labeling for such products. It is also essential that manufacturers, prior to marketing such products, be required to demonstrate that such products will meet a series of rigorous criteria, and will benefit the health of the population as a whole, taking into account both users of tobacco products and persons who do not currently use tobacco products.

(37) Unless tobacco products that purport to reduce the risks to the public of tobacco use actually reduce such risks, those products can cause substantial harm to the public health to the extent that the individuals, who would otherwise not consume tobacco products or would consume such products less, use tobacco products purporting to reduce risk. Those who use products sold or distributed as modified risk products that do not in fact reduce risk, rather than quitting or reducing their use of tobacco products, have a substantially increased likelihood of suffering disability and premature death. The costs to society of the widespread use of products sold or distributed as modified risk products that do not in fact reduce risk or that increase risk include thousands of unnecessary deaths and injuries and huge costs to our health care system.

(38) As the National Cancer Institute has found, many smokers mistakenly believe that ''low tar'' and ''light'' cigarettes cause fewer health problems than other cigarettes. As the National Cancer Institute has also found, mistaken beliefs about the health consequences of smoking ''low tar'' and ''light'' cigarettes can reduce the motivation to quit smoking entirely and thereby lead to disease and death.

(39) Recent studies have demonstrated that there has been no reduction in risk on a population-wide basis from ''low tar'' and ''light'' cigarettes, and such products may actually increase the risk of tobacco use.

(40) The dangers of products sold or distributed as modified risk tobacco products that do not in fact reduce risk are so high that there is a compelling governmental interest in ensuring that statements about modified risk tobacco products are complete, accurate, and relate to the overall disease risk of the product.

(41) As the Federal Trade Commission has found, consumers have misinterpreted advertisements in which one product is claimed to be less harmful than a comparable product, even in the presence of disclosures and advisories intended to provide clarification.

(42) Permitting manufacturers to make unsubstantiated statements concerning modified risk tobacco products, whether express or implied, even if accompanied by disclaimers would be detrimental to the public health.

(43) The only way to effectively protect the public health from the dangers of unsubstantiated modified risk tobacco products is to empower the Food and Drug Administration to require that products that tobacco manufacturers sold or distributed for risk reduction be reviewed in advance of marketing, and to require that the evidence relied on to support claims be fully verified.

(44) The Food and Drug Administration is a regulatory agency with the scientific expertise to identify harmful substances in products to which consumers are exposed, to design standards to limit exposure to those substances, to evaluate scientific studies supporting claims about the safety of products, and to evaluate the impact of labels, labeling, and advertising on consumer behavior in order to reduce the risk of harm and promote understanding of the impact of the product on health. In connection with its mandate to promote health and reduce the risk of harm, the Food and Drug Administration routinely makes decisions about whether and how products may be marketed in the United States.

(45) The Federal Trade Commission was created to protect consumers from unfair or deceptive acts or practices, and to regulate unfair methods of competition. Its focus is on those marketplace practices that deceive or mislead consumers, and those that give some competitors an unfair advantage. Its mission is to regulate activities in the marketplace. Neither the Federal Trade Commission nor any other Federal agency except the Food and Drug Administration possesses the scientific expertise needed to implement effectively all provisions of the Family Smoking Prevention and Tobacco Control Act.

(46) If manufacturers state or imply in communications directed to consumers through the media or through a label, labeling, or advertising, that a tobacco product is approved or inspected by the Food and Drug Administration or complies with Food and Drug Administration standards, consumers are likely to be confused and misled. Depending upon the particular language used and its context, such a statement could result in consumers being misled into believing that the product is endorsed by the Food and Drug Administration for use or in consumers being misled about the harmfulness of the product because of such regulation, inspection, approval, or compliance.

(47) In August 2006 a United States district court judge found that the major United States cigarette companies continue to target and market to youth. USA v. Philip Morris, USA, Inc., et al. (Civil Action No. 99–2496 (GK), August 17, 2006).

(48) In August 2006 a United States district court judge found that the major United States cigarette companies dramatically increased their advertising and promotional spending in ways that encourage youth to start smoking subsequent to the signing of the Master Settlement Agreement in 1998. USA v. Philip Morris, USA, Inc., et al. (Civil Action No. 99–2496 (GK), August 17, 2006).

(49) In August 2006 a United States district court judge found that the major United States cigarette companies have designed their cigarettes to precisely control nicotine delivery levels and provide doses of nicotine sufficient to create and sustain addiction while also concealing much of their nicotine-related research. USA v. Philip Morris, USA, Inc., et al. (Civil Action No. 99–2496 (GK), August 17, 2006).

SEC. 3. PURPOSE.

The purposes of this division are—

(1) to provide authority to the Food and Drug Administration to regulate tobacco products under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.), by recognizing it as the primary Federal regulatory authority with respect to the manufacture, marketing, and distribution of tobacco products as provided for in this division;

(2) to ensure that the Food and Drug Administration has the authority to address issues of particular concern to public health officials, especially the use of tobacco by young people and dependence on tobacco;

(3) to authorize the Food and Drug Administration to set national standards controlling the manufacture of tobacco products and the identity, public disclosure, and amount of ingredients used in such products;

(4) to provide new and flexible enforcement authority to ensure that there is effective oversight of the tobacco industry's efforts to develop, introduce, and promote less harmful tobacco products;

(5) to vest the Food and Drug Administration with the authority to regulate the levels of tar, nicotine, and other harmful components of tobacco products;

(6) in order to ensure that consumers are better informed, to require tobacco product manufacturers to disclose research which has not previously been made available, as well as research generated in the future, relating to the health and dependency effects or safety of tobacco products;

(7) to continue to permit the sale of tobacco products to adults in conjunction with measures to ensure that they are not sold or accessible to underage purchasers;

(8) to impose appropriate regulatory controls on the tobacco industry;

(9) to promote cessation to reduce disease risk and the social costs associated with tobacco-related diseases; and

(10) to strengthen legislation against illicit trade in tobacco products.

SEC. 4. SCOPE AND EFFECT.

(a) INTENDED EFFECT.—Nothing in this division (or an amendment made by this division) shall be construed to—

(1) establish a precedent with regard to any other industry, situation, circumstance, or legal action; or

(2) affect any action pending in Federal, State, or tribal court, or any agreement, consent decree, or contract of any kind.

(b) AGRICULTURAL ACTIVITIES.—The provisions of this division (or an amendment made by this division) which authorize the Secretary to take certain actions with regard to tobacco and tobacco products shall not be construed to affect any authority of the Secretary of Agriculture under existing law regarding the growing, cultivation, or curing of raw tobacco.

(c) REVENUE ACTIVITIES.—The provisions of this division (or an amendment made by this division) which authorize the Secretary to take certain actions with regard to tobacco products shall not be construed to affect any authority of the Secretary of the Treasury under chapter 52 of the Internal Revenue Code of 1986.

SEC. 5. SEVERABILITY.

If any provision of this division, of the amendments made by this division, or of the regulations promulgated under this division (or under such amendments), or the application of any such provision to any person or circumstance is held to be invalid, the remainder of this division, such amendments and such regulations, and the application of such provisions to any other person or circumstance shall not be affected and shall continue to be enforced to the fullest extent possible.

SEC. 6. MODIFICATION OF DEADLINES FOR SECRETARIAL ACTION.

(a) DELAYED COMMENCEMENT OF DATES FOR SECRETARIAL ACTION.—

(1) IN GENERAL.—Except as provided in subsection (c), with respect to any time periods specified in this division (or in an amendment made by this division) that begin on the date of enactment of this Act, within which the Secretary of Health and Human Services is required to carry out and complete specified activities, the calculation of such time periods shall commence on the date described in subsection (b).

(2) LIMITATION.—Subsection (a) shall only apply with respect to obligations of the Secretary of Health and Human Services that must be completed within a specified time period and shall not apply to the obligations of any other person or to any other provision of this division (including the amendments made by this division) that do not create such obligations of the Secretary and are not contingent on actions by the Secretary.

(b) DATE DESCRIBED.—The date described in this subsection is the first day of the first fiscal quarter following the initial 2 consecutive fiscal quarters of fiscal year 2010 for which the Secretary of Health and Human Services has collected fees under section 919 of the Federal Food, Drug, and Cosmetic Act (as added by section 101).

(c) EXCEPTION.—Subsection (a) shall not apply to any time period (or date) contained—

(1) in section 102, except that the reference to ''180 days'' in subsection (a)(1) of such section shall be deemed to be ''270 days''; and

(2) in sections 201 through 204 (or the amendments made by any such sections).

(d) ADJUSTMENT.—The Secretary of Health and Human Services may extend or reduce the duration of one or more time periods to which subsection (a) applies if the Secretary determines appropriate, except that no such period shall be extended for more than 90 days.

TITLE I—AUTHORITY OF THE FOOD AND DRUG ADMINISTRATION

SEC. 101. AMENDMENT OF FEDERAL FOOD, DRUG, AND COSMETIC ACT.

(a) DEFINITION OF TOBACCO PRODUCTS.—Section 201 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321) is amended by adding at the end the following:

''(rr)(1) The term 'tobacco product' means any product made or derived from tobacco that is intended for human consumption, including any component, part, or accessory of a tobacco product (except for raw materials other than tobacco used in manufacturing a component, part, or accessory of a tobacco product).

''(2) The term 'tobacco product' does not mean an article that is a drug under subsection (g)(1), a device under subsection (h), or a combination product described in section 503(g).

''(3) The products described in paragraph (2) shall be subject to chapter V of this Act.

''(4) A tobacco product shall not be marketed in combination with any other article or product regulated under this Act (including a drug, biologic, food, cosmetic, medical device, or a dietary supplement).''.

(b) FDA AUTHORITY OVER TOBACCO PRODUCTS.—The Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.) is amended—

(1) by redesignating chapter IX as chapter X;

(2) by redesignating sections 901 through 910 as sections 1001 through 1010; and

(3) by inserting after chapter VIII the following:

''CHAPTER IX—TOBACCO PRODUCTS

''SEC. 900. DEFINITIONS.

''In this chapter:

''(1) ADDITIVE.—The term 'additive' means any substance the intended use of which results or may reasonably be expected to result, directly or indirectly, in its becoming a component or otherwise affecting the characteristic of any tobacco product (including any substances intended for use as a flavoring or coloring or in producing, manufacturing, packing, processing, preparing, treating, packaging, transporting, or holding), except that such term does not include tobacco or a pesticide chemical residue in or on raw tobacco or a pesticide chemical.

''(2) BRAND.—The term 'brand' means a variety of tobacco product distinguished by the tobacco used, tar content, nicotine content, flavoring used, size, filtration, packaging, logo, registered trademark, brand name, identifiable pattern of colors, or any combination of such attributes.

''(3) CIGARETTE.—The term 'cigarette'—

''(A) means a product that—

''(i) is a tobacco product; and

''(ii) meets the definition of the term 'cigarette' in section 3(1) of the Federal Cigarette Labeling and Advertising Act; and

''(B) includes tobacco, in any form, that is functional in the product, which, because of its appearance, the type of tobacco used in the filler, or its packaging and labeling, is likely to be offered to, or purchased by, consumers as a cigarette or as roll-your-own tobacco.

''(4) CIGARETTE TOBACCO.—The term 'cigarette tobacco' means any product that consists of loose tobacco that is intended for use by consumers in a cigarette. Unless otherwise stated, the requirements applicable to cigarettes under this chapter shall also apply to cigarette tobacco.

''(5) COMMERCE.—The term 'commerce' has the meaning given that term by section 3(2) of the Federal Cigarette Labeling and Advertising Act.

''(6) COUNTERFEIT TOBACCO PRODUCT.—The term 'counterfeit tobacco product' means a tobacco product (or the container or labeling of such a product) that, without authorization, bears the trademark, trade name, or other identifying mark, imprint, or device, or any likeness thereof, of a tobacco product listed in a registration under section 905(i)(1).

''(7) DISTRIBUTOR.—The term 'distributor' as regards a tobacco product means any person who furthers the distribution of a tobacco product, whether domestic or imported, at any point from the original place of manufacture to the person who sells or distributes the product to individuals for personal consumption. Common carriers are not considered distributors for purposes of this chapter.

''(8) ILLICIT TRADE.—The term 'illicit trade' means any practice or conduct prohibited by law which relates to production, shipment, receipt, possession, distribution, sale, or purchase of tobacco products including any practice or conduct intended to facilitate such activity.

''(9) INDIAN COUNTRY.—The term 'Indian country' has the meaning given such term in section 1151 of title 18, United States Code.

''(10) INDIAN TRIBE.—The term 'Indian tribe' has the meaning given such term in section 4(e) of the Indian Self-Determination and Education Assistance Act.

''(11) LITTLE CIGAR.—The term 'little cigar' means a product that—

''(A) is a tobacco product; and

''(B) meets the definition of the term 'little cigar' in section 3(7) of the Federal Cigarette Labeling and Advertising Act.

''(12) NICOTINE.—The term 'nicotine' means the chemical substance named 3-(1-Methyl-2-pyrrolidinyl) pyridine or C[10]H[14]N[2], including any salt or complex of nicotine.

''(13) PACKAGE.—The term 'package' means a pack, box, carton, or container of any kind or, if no other container, any wrapping (including cellophane), in which a tobacco product is offered for sale, sold, or otherwise distributed to consumers.

''(14) RETAILER.—The term 'retailer' means any person, government, or entity who sells tobacco products to individuals for personal consumption, or who operates a facility where self-service displays of tobacco products are permitted.

''(15) ROLL-YOUR-OWN TOBACCO.—The term 'roll-your-own tobacco' means any tobacco product which, because of its appearance, type, packaging, or labeling, is suitable for use and likely to be offered to, or purchased by, consumers as tobacco for making cigarettes.

''(16) SMALL TOBACCO PRODUCT MANUFACTURER.—The term 'small tobacco product manufacturer' means a tobacco product manufacturer that employs fewer than 350 employees. For purposes of determining the number of employees of a manufacturer under the preceding sentence, the employees of a manufacturer are deemed to include the

employees of each entity that controls, is controlled by, or is under common control with such manufacturer.

''(17) SMOKE CONSTITUENT.—The term 'smoke constituent' means any chemical or chemical compound in mainstream or sidestream tobacco smoke that either transfers from any component of the cigarette to the smoke or that is formed by the combustion or heating of tobacco, additives, or other component of the tobacco product.

''(18) SMOKELESS TOBACCO.—The term 'smokeless tobacco' means any tobacco product that consists of cut, ground, powdered, or leaf tobacco and that is intended to be placed in the oral or nasal cavity.

''(19) STATE; TERRITORY.—The terms 'State' and 'Territory' shall have the meanings given to such terms in section 201.

''(20) TOBACCO PRODUCT MANUFACTURER.—The term 'tobacco product manufacturer' means any person, including any repacker or relabeler, who—

''(A) manufactures, fabricates, assembles, processes, or labels a tobacco product; or

''(B) imports a finished tobacco product for sale or distribution in the United States.

''(21) TOBACCO WAREHOUSE.—

''(A) Subject to subparagraphs (B) and (C), the term 'tobacco warehouse' includes any person—

''(i) who—

''(I) removes foreign material from tobacco leaf through nothing other than a mechanical process;

''(II) humidifies tobacco leaf with nothing other than potable water in the form of steam or mist; or

''(III) de-stems, dries, and packs tobacco leaf for storage and shipment;

''(ii) who performs no other actions with respect to tobacco leaf; and

''(iii) who provides to any manufacturer to whom the person sells tobacco all information related to the person's actions described in clause (i) that is necessary for compliance with this Act.

''(B) The term 'tobacco warehouse' excludes any person who—

''(i) reconstitutes tobacco leaf;

''(ii) is a manufacturer, distributor, or retailer of a tobacco product; or

''(iii) applies any chemical, additive, or substance to the tobacco leaf other than potable water in the form of steam or mist.

''(C) The definition of the term 'tobacco warehouse' in subparagraph (A) shall not apply to the extent to which the Secretary determines, through rulemaking, that regulation under this chapter of the actions described in such subparagraph is appropriate for the protection of the public health.

''(22) UNITED STATES.—The term 'United States' means the 50 States of the United States of America and the District of Columbia, the Commonwealth of Puerto Rico, Guam, the Virgin Islands, American Samoa, Wake Island, Midway Islands, Kingman Reef, Johnston Atoll, the Northern Mariana Islands, and any other trust territory or possession of the United States.

''SEC. 901. FDA AUTHORITY OVER TOBACCO PRODUCTS.

''(a) IN GENERAL.—Tobacco products, including modified risk tobacco products for which an order has been issued in accordance with section 911, shall be regulated by the Secretary under this chapter and shall not be subject to the provisions of chapter V.

''(b) APPLICABILITY.—This chapter shall apply to all cigarettes, cigarette tobacco, roll-your-own tobacco, and smokeless tobacco and to any other tobacco products that the Secretary by regulation deems to be subject to this chapter.

''(c) SCOPE.—

''(1) IN GENERAL.—Nothing in this chapter, or any policy issued or regulation promulgated thereunder, or in sections 101(a), 102, or 103 of title I, title II, or title III of the Family Smoking Prevention and Tobacco Control Act, shall be construed to affect, expand, or limit the Secretary's authority over (including the authority to determine whether products may be regulated), or the regulation of, products under this Act that are not tobacco products under chapter V or any other chapter.

''(2) LIMITATION OF AUTHORITY.—

''(A) IN GENERAL.—The provisions of this chapter shall not apply to tobacco leaf that is not in the possession of a manufacturer of tobacco products, or to the producers of tobacco leaf, including tobacco growers, tobacco warehouses, and tobacco grower cooperatives, nor shall any employee of the Food and Drug Administration have any authority to enter onto a farm owned by a producer of tobacco leaf without the written consent of such producer.

''(B) EXCEPTION.—Notwithstanding subparagraph (A), if a producer of tobacco leaf is also a tobacco product manufacturer or controlled by a tobacco product manufacturer, the producer shall be subject to this chapter in the producer's capacity as a manufacturer. The exception in this subparagraph shall not apply to a producer of tobacco leaf who grows tobacco under a contract with a tobacco product manufacturer and who is not otherwise engaged in the manufacturing process.

''(C) RULE OF CONSTRUCTION.—Nothing in this chapter shall be construed to grant the Secretary authority to promulgate regulations on any matter that involves the production of tobacco leaf or a producer thereof, other than activities by a manufacturer affecting production.

''(d) RULEMAKING PROCEDURES.—Each rulemaking under this chapter shall be in accordance with chapter 5 of title 5, United States Code. This subsection shall not be construed to affect the rulemaking provisions of section 102(a) of the Family Smoking Prevention and Tobacco Control Act.

''(e) CENTER FOR TOBACCO PRODUCTS.—Not later than 90 days after the date of enactment of the Family Smoking Prevention and Tobacco Control Act, the Secretary shall establish within the Food and Drug Administration the Center for Tobacco Products, which shall report to the Commissioner of Food and Drugs in the same manner as the other agency centers within the Food and Drug Administration. The Center shall be responsible for the implementation of this chapter and related matters assigned by the Commissioner.

''(f) OFFICE TO ASSIST SMALL TOBACCO PRODUCT MANUFACTURERS.—The Secretary shall establish within the Food and Drug Administration an identifiable office to provide technical and other nonfinancial assistance to small tobacco product manufacturers to assist them in complying with the requirements of this Act.

''(g) CONSULTATION PRIOR TO RULEMAKING.—Prior to promulgating rules under this chapter, the Secretary shall endeavor to consult with other Federal agencies as appropriate.

''SEC. 902. ADULTERATED TOBACCO PRODUCTS.

''A tobacco product shall be deemed to be adulterated if—

''(1) it consists in whole or in part of any filthy, putrid, or decomposed substance, or is otherwise contaminated by any added poisonous or added deleterious substance that may render the product injurious to health;

''(2) it has been prepared, packed, or held under insanitary conditions whereby it may have been contaminated with filth, or whereby it may have been rendered injurious to health;

''(3) its package is composed, in whole or in part, of any poisonous or deleterious substance which may render the contents injurious to health;

''(4) the manufacturer or importer of the tobacco product fails to pay a user fee assessed to such manufacturer or importer pursuant to section 919 by the date specified in section 919 or by the 30th day after final agency action on a resolution of any dispute as to the amount of such fee;

''(5) it is, or purports to be or is represented as, a tobacco product which is subject to a tobacco product standard established under section 907 unless such tobacco product is in all respects in conformity with such standard;

''(6)(A) it is required by section 910(a) to have premarket review and does not have an order in effect under section 910(c)(1)(A)(i); or

''(B) it is in violation of an order under section 910(c)(1)(A);

''(7) the methods used in, or the facilities or controls used for, its manufacture, packing, or storage are not in conformity with applicable requirements under section 906(e)(1) or an applicable condition prescribed by an order under section 906(e)(2); or

''(8) it is in violation of section 911.

''SEC. 903. MISBRANDED TOBACCO PRODUCTS.

''(a) IN GENERAL.—A tobacco product shall be deemed to be misbranded—

''(1) if its labeling is false or misleading in any particular;

''(2) if in package form unless it bears a label containing—

''(A) the name and place of business of the tobacco product manufacturer, packer, or distributor;

''(B) an accurate statement of the quantity of the contents in terms of weight, measure, or numerical count;

''(C) an accurate statement of the percentage of the tobacco used in the product that is domestically grown tobacco and the percentage that is foreign grown tobacco; and

''(D) the statement required under section 920(a),

except that under subparagraph (B) reasonable variations shall be permitted, and exemptions as to small packages shall be established, by regulations prescribed by the Secretary;

''(3) if any word, statement, or other information required by or under authority of this chapter to appear on the label or labeling is not prominently placed thereon with such conspicuousness (as compared with other words, statements, or designs in the labeling) and in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use;

''(4) if it has an established name, unless its label bears, to the exclusion of any other nonproprietary name, its established name prominently printed in type as required by the Secretary by regulation;

''(5) if the Secretary has issued regulations requiring that its labeling bear adequate directions for use, or adequate warnings against use by children, that are necessary for the protection of users unless its labeling conforms in all respects to such regulations;

''(6) if it was manufactured, prepared, propagated, compounded, or processed in an establishment not duly registered under section 905(b), 905(c), 905(d), or 905(h), if it was not included in a list required by section 905(i), if a notice or other information respecting it was not provided as required by such section or section 905(j), or if it does not bear such symbols from the uniform system for identification of tobacco products prescribed under section 905(e) as the Secretary by regulation requires;

''(7) if, in the case of any tobacco product distributed or offered for sale in any State—

''(A) its advertising is false or misleading in any particular; or

''(B) it is sold or distributed in violation of regulations prescribed under section 906(d);

''(8) unless, in the case of any tobacco product distributed or offered for sale in any State, the manufacturer, packer, or distributor thereof includes in all advertisements and other descriptive printed matter issued or caused to be issued by the manufacturer, packer, or distributor with respect to that tobacco product—

''(A) a true statement of the tobacco product's established name as described in paragraph (4), printed prominently; and

''(B) a brief statement of—

''(i) the uses of the tobacco product and relevant warnings, precautions, side effects, and contraindications; and

''(ii) in the case of specific tobacco products made subject to a finding by the Secretary after notice and opportunity for comment that such action is appropriate to protect the public health, a full description of the components of such tobacco product or the formula showing quantitatively each ingredient of such tobacco product to the extent required in regulations which shall be issued by the Secretary after an opportunity for a hearing;

''(9) if it is a tobacco product subject to a tobacco product standard established under section 907, unless it bears such labeling as may be prescribed in such tobacco product standard; or

''(10) if there was a failure or refusal—

''(A) to comply with any requirement prescribed under section 904 or 908; or

''(B) to furnish any material or information required under section 909.

''(b) PRIOR APPROVAL OF LABEL STATEMENTS.—The Secretary may, by regulation, require prior approval of statements made on the label of a tobacco product to ensure that such statements do not violate the misbranding provisions of subsection (a) and that such statements comply with other provisions of the Family Smoking Prevention and Tobacco Control Act (including the amendments made by such Act). No regulation issued under this subsection may require prior approval by the Secretary of the content of any advertisement, except for modified risk tobacco products as provided in section 911. No advertisement of a tobacco product published after the date of enactment of the Family Smoking Prevention and Tobacco Control Act shall, with respect to the language of label statements as prescribed under section 4 of the Federal Cigarette Labeling and Advertising Act and section 3 of the Comprehensive Smokeless Tobacco Health Education Act of 1986 or the regulations issued under such sections, be subject to the provisions of sections 12 through 15 of the Federal Trade Commission Act.

''SEC. 904. SUBMISSION OF HEALTH INFORMATION TO THE SECRETARY.

''(a) REQUIREMENT.—Each tobacco product manufacturer or importer, or agents thereof, shall submit to the Secretary the following information:

''(1) Not later than 6 months after the date of enactment of the Family Smoking Prevention and Tobacco Control Act, a listing of all ingredients, including tobacco, substances, compounds, and additives that are, as of such date, added by the manufacturer to the tobacco, paper, filter, or other part of each tobacco product by brand and by quantity in each brand and subbrand.

''(2) A description of the content, delivery, and form of nicotine in each tobacco product measured in milligrams of nicotine in accordance with regulations promulgated by the Secretary in accordance with section 4(e) of the Federal Cigarette Labeling and Advertising Act.

''(3) Beginning 3 years after the date of enactment of the Family Smoking Prevention and Tobacco Control Act, a listing of all constituents, including smoke constituents as applicable, identified by the Secretary as harmful or potentially harmful to health in each tobacco product, and as applicable in the smoke of each tobacco product, by brand and by quantity in each brand and subbrand. Effective beginning 3 years after such date of enactment, the manufacturer, importer, or agent shall comply with regulations promulgated under section 915 in reporting information under this paragraph, where applicable.

''(4) Beginning 6 months after the date of enactment of the Family Smoking Prevention and Tobacco Control Act, all documents developed after such date of enactment that relate to health, toxicological, behavioral, or physiologic effects of current or future tobacco products, their constituents (including smoke constituents), ingredients, components, and additives.

''(b) DATA SUBMISSION.—At the request of the Secretary, each tobacco product manufacturer or importer of tobacco products, or agents thereof, shall submit the following:

''(1) Any or all documents (including underlying scientific information) relating to research activities, and research findings, conducted, supported, or possessed by the manufacturer (or agents thereof) on the health, toxicological, behavioral, or physiologic effects of tobacco products and their constituents (including smoke constituents), ingredients, components, and additives.

''(2) Any or all documents (including underlying scientific information) relating to research activities, and research findings, conducted, supported, or possessed by the manufacturer (or agents thereof) that relate to the issue of whether a reduction in risk to health from tobacco products can occur upon the employment of technology available or known to the manufacturer.

''(3) Any or all documents (including underlying scientific or financial information) relating to marketing research involving the use of tobacco products or marketing practices and the effectiveness of such practices used by tobacco manufacturers and distributors.

An importer of a tobacco product not manufactured in the United States shall supply the information required of a tobacco product manufacturer under this subsection.

''(c) TIME FOR SUBMISSION.—

''(1) IN GENERAL.—At least 90 days prior to the delivery for introduction into interstate commerce of a tobacco product not on the market on the date of enactment of the Family Smoking Prevention and Tobacco Control Act, the manufacturer of such product shall provide the information required under subsection (a).

''(2) DISCLOSURE OF ADDITIVE.—If at any time a tobacco product manufacturer adds to its tobacco products a new tobacco additive or increases the quantity of an existing tobacco additive, the manufacturer shall, except as provided in paragraph (3), at least 90 days prior to such action so advise the Secretary in writing.

''(3) DISCLOSURE OF OTHER ACTIONS.—If at any time a tobacco product manufacturer eliminates or decreases an existing additive, or adds or increases an additive that has by regulation been designated by the Secretary as an additive that is not a human or animal carcinogen, or otherwise harmful to health under intended conditions of use, the manufacturer shall within 60 days of such action so advise the Secretary in writing.

''(d) DATA LIST.—

''(1) IN GENERAL.—Not later than 3 years after the date of enactment of the Family Smoking Prevention and Tobacco Control Act, and annually thereafter, the Secretary shall publish in a format that is understandable and not misleading to a lay person, and place on public display (in a manner determined by the Secretary) the list established under subsection (e).

''(2) CONSUMER RESEARCH.—The Secretary shall conduct periodic consumer research to ensure that the list published under paragraph (1) is not misleading to lay persons. Not later than 5 years after the date of enactment of the Family Smoking Prevention and Tobacco Control Act, the Secretary shall submit to the appropriate committees of Congress a report on the results of such research, together with recommendations on whether such publication should be continued or modified.

''(e) DATA COLLECTION.—Not later than 24 months after the date of enactment of the Family Smoking Prevention and Tobacco Control Act, the Secretary shall establish, and periodically revise as appropriate, a list of harmful and potentially harmful constituents, including smoke constituents, to health in each tobacco product by brand and by quantity in each brand and subbrand. The Secretary shall publish a public notice requesting the submission by interested persons of scientific and other information concerning the harmful and potentially harmful constituents in tobacco products and tobacco smoke.

''SEC. 905. ANNUAL REGISTRATION.

''(a) DEFINITIONS.—In this section:

''(1) MANUFACTURE, PREPARATION, COMPOUNDING, OR PROCESSING.—The term 'manufacture, preparation, compounding, or processing' shall include repackaging or otherwise changing the container, wrapper, or labeling of any tobacco product package in furtherance of the distribution of the tobacco product from the original place of manufacture to the person who makes final delivery or sale to the ultimate consumer or user.

''(2) NAME.—The term 'name' shall include in the case of a partnership the name of each partner and, in the case of a corporation, the name of each corporate officer and director, and the State of incorporation.

''(b) REGISTRATION BY OWNERS AND OPERATORS.—On or before December 31 of each year, every person who owns or operates any establishment in any State engaged in the manufacture, preparation, compounding, or processing of a tobacco product or tobacco products shall register with the Secretary the name, places of business, and all such establishments of that person. If enactment of the Family Smoking Prevention and Tobacco Control Act occurs in the second half of the calendar year, the Secretary shall designate a date no later than 6 months into the subsequent calendar year by which registration pursuant to this subsection shall occur.

''(c) REGISTRATION BY NEW OWNERS AND OPERATORS.—Every person upon first engaging in the manufacture, preparation, compounding, or processing of a tobacco product or tobacco products in any establishment owned or operated in any State by that person shall immediately register with the Secretary that person's name, place of business, and such establishment.

''(d) REGISTRATION OF ADDED ESTABLISHMENTS.—Every person required to register under subsection (b) or (c) shall immediately register with the Secretary any additional establishment which that person owns or operates in any State and in which that person begins the manufacture, preparation, compounding, or processing of a tobacco product or tobacco products.

''(e) UNIFORM PRODUCT IDENTIFICATION SYSTEM.—The Secretary may by regulation prescribe a uniform system for the identification of tobacco products and may require that persons who are required to list such tobacco products under subsection (i) shall list such tobacco products in accordance with such system.

''(f) PUBLIC ACCESS TO REGISTRATION INFORMATION.—The Secretary shall make available for inspection, to any person so requesting, any registration filed under this section.

''(g) BIENNIAL INSPECTION OF REGISTERED ESTABLISHMENTS.—Every establishment registered with the Secretary under this section shall be subject to inspection under section 704 or subsection (h), and every such establishment engaged in the manufacture, compounding, or processing of a tobacco product or tobacco products shall be so inspected by 1 or more officers or employees duly designated by the Secretary at least once in the 2-year period beginning with the date of registration of such establishment under this section and at least once in every successive 2-year period thereafter.

''(h) REGISTRATION BY FOREIGN ESTABLISHMENTS.—Any establishment within any foreign country engaged in the manufacture, preparation, compounding, or processing of a tobacco product or tobacco products, shall register under this section under regulations promulgated by the Secretary. Such regulations shall require such establishment to provide the information required by subsection (i) and shall include provisions for registration of any such establishment upon condition that adequate and effective means are available, by arrangement with the government of such foreign country or otherwise, to enable the Secretary to determine from time to time whether tobacco products manufactured, prepared, compounded, or processed in such establishment, if imported or offered for import into the United States, shall be refused admission on any of the grounds set forth in section 801(a).

''(i) REGISTRATION INFORMATION.—

''(1) PRODUCT LIST.—Every person who registers with the Secretary under subsection (b), (c), (d), or (h) shall, at the time of registration under any such subsection, file with the Secretary a list of all tobacco products which are being manufactured, prepared, compounded, or processed by that person for commercial distribution and which have not been included in any list of tobacco products filed by that person with the Secretary under this paragraph or paragraph (2) before such time of registration. Such list shall be prepared in such form and manner as the Secretary may prescribe and shall be accompanied by—

''(A) in the case of a tobacco product contained in the applicable list with respect to which a tobacco product standard has been established under section 907 or which is subject to section 910, a reference to the authority for the marketing of such tobacco product and a copy of all labeling for such tobacco product;

''(B) in the case of any other tobacco product contained in an applicable list, a copy of all consumer information and other labeling for such tobacco product, a representative sampling of advertisements for such tobacco product, and, upon request made by the Secretary for good cause, a copy of all advertisements for a particular tobacco product; and

''(C) if the registrant filing a list has determined that a tobacco product contained in such list is not subject to a tobacco product standard established under section 907, a brief statement of the basis upon which the registrant made such determination if the Secretary requests such a statement with respect to that particular tobacco product.

''(2) CONSULTATION WITH RESPECT TO FORMS.—The Secretary shall consult with the Secretary of the Treasury in developing the forms to be used for registration under this section to minimize the burden on those persons required to register with both the Secretary and the Tax and Trade Bureau of the Department of the Treasury.

''(3) BIANNUAL REPORT OF ANY CHANGE IN PRODUCT LIST.—Each person who registers with the Secretary under this section shall report to the Secretary once during the month of June of each year and once during the month of December of each year the following:

''(A) A list of each tobacco product introduced by the registrant for commercial distribution which has not been included in any list previously filed by that person with the Secretary under this subparagraph or paragraph (1). A list under this subparagraph shall list a tobacco product by its established name and shall be accompanied by the other information required by paragraph (1).

''(B) If since the date the registrant last made a report under this paragraph that person has discontinued the manufacture, preparation, compounding, or processing for commercial distribution of a tobacco product included in a list filed under subparagraph (A) or paragraph (1), notice of such discontinuance, the date of such discontinuance, and the identity of its established name.

''(C) If since the date the registrant reported under subparagraph (B) a notice of discontinuance that person has resumed the manufacture, preparation, compounding, or processing for commercial distribution of the tobacco product with respect to which such notice of discontinuance was reported, notice of such resumption, the date of such resumption, the identity of such tobacco product by established name, and other information required by paragraph (1), unless the registrant has previously reported such resumption to the Secretary under this subparagraph.

''(D) Any material change in any information previously submitted under this paragraph or paragraph (1).

''(j) REPORT PRECEDING INTRODUCTION OF CERTAIN SUBSTANTIALLY EQUIVALENT PRODUCTS INTO INTERSTATE COMMERCE.—

''(1) IN GENERAL.—Each person who is required to register under this section and who proposes to begin the introduction or delivery for introduction into interstate commerce for commercial distribution of a tobacco product intended for human use that was not commercially marketed (other than for test marketing) in the United States as of February 15, 2007, shall, at least 90 days prior to making such introduction or delivery, report to the Secretary (in such form and manner as the Secretary shall prescribe)—

''(A) the basis for such person's determination that—

''(i) the tobacco product is substantially equivalent, within the meaning of section 910, to a tobacco product commercially marketed (other than for test marketing) in the United States as of February 15, 2007, or to a tobacco product that the Secretary has previously determined, pursuant to subsection (a)(3) of section 910, is substantially equivalent and that is in compliance with the requirements of this Act; or

''(ii) the tobacco product is modified within the meaning of paragraph (3), the modifications are to a product that is commercially marketed and in compliance with the requirements of this Act, and all of the modifications are covered by exemptions granted by the Secretary pursuant to paragraph (3); and

''(B) action taken by such person to comply with the requirements under section 907 that are applicable to the tobacco product.

''(2) APPLICATION TO CERTAIN POST-FEBRUARY 15, 2007, PRODUCTS.—A report under this subsection for a tobacco product that was first introduced or delivered for introduction into interstate commerce for commercial distribution in the United States after February 15, 2007, and prior to the date that is 21 months after the date of enactment of the Family Smoking Prevention and Tobacco Control Act shall be submitted to the Secretary not later than 21 months after such date of enactment.

''(3) EXEMPTIONS.—

''(A) IN GENERAL.—The Secretary may exempt from the requirements of this subsection relating to the demonstration that a tobacco product is substantially equivalent within the meaning of section 910, tobacco products that are modified by adding or deleting a tobacco additive, or increasing or decreasing the quantity of an existing tobacco additive, if the Secretary determines that—

''(i) such modification would be a minor modification of a tobacco product that can be sold under this Act;

''(ii) a report under this subsection is not necessary to ensure that permitting the tobacco product to be marketed would be appropriate for protection of the public health; and

''(iii) an exemption is otherwise appropriate.

''(B) REGULATIONS.—Not later than 15 months after the date of enactment of the Family Smoking Prevention and Tobacco Control Act, the Secretary shall issue regulations to implement this paragraph.

''SEC. 906. GENERAL PROVISIONS RESPECTING CONTROL OF TOBACCO PRODUCTS.

''(a) IN GENERAL.—Any requirement established by or under section 902, 903, 905, or 909 applicable to a tobacco product shall apply to such tobacco product until the applicability of the requirement to the tobacco product has been changed by action taken under section 907, section 910, section 911, or subsection (d) of this section, and any requirement established by or under section 902, 903, 905, or 909 which is inconsistent with a requirement imposed on such tobacco product under section 907, section 910, section 911, or subsection (d) of this section shall not apply to such tobacco product.

''(b) INFORMATION ON PUBLIC ACCESS AND COMMENT.—Each notice of proposed rulemaking or other notification under section 907, 908, 909, 910, or 911 or under this section, any other notice which is published in the Federal Register with respect to any other action taken under any such section and which states the reasons for such action, and each publication of findings required to be made in connection with rulemaking under any such section shall set forth—

''(1) the manner in which interested persons may examine data and other information on which the notice or findings is based; and

''(2) the period within which interested persons may present their comments on the notice or findings (including the need therefore) orally or in writing, which period shall be at least 60 days but may not exceed 90 days unless the time is extended by the Secretary by a notice published in the Federal Register stating good cause therefore.

''(c) LIMITED CONFIDENTIALITY OF INFORMATION.—Any information reported to or otherwise obtained by the Secretary or the Secretary's representative under section 903, 904, 907, 908, 909, 910, 911, or 704, or under subsection (e) or (f) of this section, which is exempt from disclosure under subsection (a) of section 552 of title 5, United States Code, by reason of subsection (b)(4) of that section shall be considered confidential and shall not be disclosed, except that the information

may be disclosed to other officers or employees concerned with carrying out this chapter, or when relevant in any proceeding under this chapter.

''(d) RESTRICTIONS.—

''(1) IN GENERAL.—The Secretary may by regulation require restrictions on the sale and distribution of a tobacco product, including restrictions on the access to, and the advertising and promotion of, the tobacco product, if the Secretary determines that such regulation would be appropriate for the protection of the public health. The Secretary may by regulation impose restrictions on the advertising and promotion of a tobacco product consistent with and to full extent permitted by the first amendment to the Constitution. The finding as to whether such regulation would be appropriate for the protection of the public health shall be determined with respect to the risks and benefits to the population as a whole, including users and nonusers of the tobacco product, and taking into account—

''(A) the increased or decreased likelihood that existing users of tobacco products will stop using such products; and

''(B) the increased or decreased likelihood that those who do not use tobacco products will start using such products.

No such regulation may require that the sale or distribution of a tobacco product be limited to the written or oral authorization of a practitioner licensed by law to prescribe medical products.

''(2) LABEL STATEMENTS.—The label of a tobacco product shall bear such appropriate statements of the restrictions required by a regulation under subsection (a) as the Secretary may in such regulation prescribe.

''(3) LIMITATIONS.—

''(A) IN GENERAL.—No restrictions under paragraph (1) may—

''(i) prohibit the sale of any tobacco product in face-to-face transactions by a specific category of retail outlets; or

''(ii) establish a minimum age of sale of tobacco products to any person older than 18 years of age.

''(B) MATCHBOOKS.—For purposes of any regulations issued by the Secretary, matchbooks of conventional size containing not more than 20 paper matches, and which are customarily given away for free with the purchase of tobacco products, shall be considered as adult-written publications which shall be permitted to contain advertising. Notwithstanding the preceding sentence, if the Secretary finds that such treatment of matchbooks is not appropriate for the protection of the public health, the Secretary may determine by regulation that matchbooks shall not be considered adult-written publications.

''(4) REMOTE SALES.—

''(A) IN GENERAL.—The Secretary shall—

''(i) within 18 months after the date of enactment of the Family Smoking Prevention and Tobacco Control Act, promulgate regulations regarding the sale and distribution of tobacco products that occur through means other than a direct, face-to-face exchange between a retailer and a consumer in order to prevent the sale and distribution of tobacco products to individuals who have not attained the minimum age established by applicable law for the purchase of such products, including requirements for age verification; and

''(ii) within 2 years after such date of enactment, issue regulations to address the promotion and marketing of tobacco products that are sold or distributed through means other than a direct, face-to-face exchange between a retailer and a consumer in order to protect individuals who have not attained the minimum age established by applicable law for the purchase of such products.

''(B) RELATION TO OTHER AUTHORITY.—Nothing in this paragraph limits the authority of the Secretary to take additional actions under the other paragraphs of this subsection.

''(e) GOOD MANUFACTURING PRACTICE REQUIREMENTS.—

''(1) METHODS, FACILITIES, AND CONTROLS TO CONFORM.—

''(A) IN GENERAL.—In applying manufacturing restrictions to tobacco, the Secretary shall, in accordance with subparagraph (B), prescribe regulations (which may differ based on the type of tobacco product involved) requiring that the methods used in, and the facilities and controls used for, the manufacture, preproduction design validation (including a process to assess the performance of a tobacco product), packing, and storage of a tobacco product conform to current good manufacturing practice, or hazard analysis and critical control point methodology, as prescribed in such regulations to assure that the public health is protected and that the tobacco product is in compliance with this chapter. Such regulations may provide for the testing of raw tobacco for pesticide chemical residues regardless of whether a tolerance for such chemical residues has been established.

''(B) REQUIREMENTS.—The Secretary shall—

''(i) before promulgating any regulation under subparagraph (A), afford the Tobacco Products Scientific Advisory Committee an opportunity to submit recommendations with respect to the regulation proposed to be promulgated;

''(ii) before promulgating any regulation under subparagraph (A), afford opportunity for an oral hearing;

''(iii) provide the Tobacco Products Scientific Advisory Committee a reasonable time to make its recommendation with respect to proposed regulations under subparagraph (A);

''(iv) in establishing the effective date of a regulation promulgated under this subsection, take into account the differences in the manner in which the different types of tobacco products have historically been produced, the financial resources of the different tobacco product manufacturers, and the state of their existing manufacturing facilities, and shall provide for a reasonable period of time for such manufacturers to conform to good manufacturing practices; and

''(v) not require any small tobacco product manufacturer to comply with a regulation under subparagraph (A) for at least 4 years following the effective date established by the Secretary for such regulation.

''(2) EXEMPTIONS; VARIANCES.—

''(A) PETITION.—Any person subject to any requirement prescribed under paragraph (1) may petition the Secretary for a permanent or temporary exemption or variance from such requirement. Such a petition shall be submitted to the Secretary in such form and manner as the Secretary shall prescribe and shall—

''(i) in the case of a petition for an exemption from a requirement, set forth the basis for the petitioner's determination that compliance with the requirement is not required to assure that the tobacco product will be in compliance with this chapter;

''(ii) in the case of a petition for a variance from a requirement, set forth the methods proposed to be used in, and the facilities and controls proposed to be used for, the manufacture, packing, and storage of the tobacco product in lieu of the methods, facilities, and controls prescribed by the requirement; and

''(iii) contain such other information as the Secretary shall prescribe.

''(B) REFERRAL TO THE TOBACCO PRODUCTS SCIENTIFIC ADVISORY COMMITTEE.—The Secretary may refer to the Tobacco Products Scientific Advisory Committee any petition submitted under subparagraph (A). The Tobacco Products Scientific Advisory Committee shall report its recommendations to the Secretary with respect to a petition referred to it within 60 days after the date of the petition's referral. Within 60 days after—

''(i) the date the petition was submitted to the Secretary under subparagraph (A); or

''(ii) the day after the petition was referred to the Tobacco Products Scientific Advisory Committee,

whichever occurs later, the Secretary shall by order either deny the petition or approve it.

''(C) APPROVAL.—The Secretary may approve—

''(i) a petition for an exemption for a tobacco product from a requirement if the Secretary determines that compliance with such requirement is not required to assure that the tobacco product will be in compliance with this chapter; and

''(ii) a petition for a variance for a tobacco product from a requirement if the Secretary determines that the methods to be used in, and the facilities and controls to be used for, the manufacture, packing, and storage of the tobacco product in lieu of the methods, facilities, and controls prescribed by the requirement are sufficient to assure that the tobacco product will be in compliance with this chapter.

''(D) CONDITIONS.—An order of the Secretary approving a petition for a variance shall prescribe such conditions respecting the methods used in, and the facilities and controls used for, the manufacture, packing, and storage of the tobacco product to be granted the variance under the petition as may be necessary to assure that the tobacco product will be in compliance with this chapter.

''(E) HEARING.—After the issuance of an order under subparagraph (B) respecting a petition, the petitioner shall have an opportunity for an informal hearing on such order.

''(3) COMPLIANCE.—Compliance with requirements under this subsection shall not be required before the end of the 3-year period following the date of enactment of the Family Smoking Prevention and Tobacco Control Act.

''(f) RESEARCH AND DEVELOPMENT.—The Secretary may enter into contracts for research, testing, and demonstrations respecting tobacco products and may obtain tobacco products for research, testing, and demonstration purposes.

''SEC. 907. TOBACCO PRODUCT STANDARDS.

''(a) IN GENERAL.—

''(1) SPECIAL RULES.—

''(A) SPECIAL RULE FOR CIGARETTES.—Beginning 3 months after the date of enactment of the Family Smoking Prevention and Tobacco Control Act, a cigarette or any of its component parts (including the tobacco, filter, or paper) shall not contain, as a constituent (including a smoke constituent) or additive, an artificial or natural flavor (other than tobacco or menthol) or an herb or spice, including strawberry, grape, orange, clove, cinnamon, pineapple, vanilla, coconut, licorice, cocoa, chocolate, cherry, or coffee, that is a characterizing flavor of the tobacco product or tobacco smoke. Nothing in this subparagraph shall be construed to limit the Secretary's authority to take action under this section or other sections of this Act applicable to menthol or any artificial or natural flavor, herb, or spice not specified in this subparagraph.

''(B) ADDITIONAL SPECIAL RULE.—Beginning 2 years after the date of enactment of the Family Smoking Prevention and Tobacco Control Act, a tobacco product manufacturer shall not use tobacco, including foreign grown tobacco, that contains a pesticide chemical residue that is at a level greater than is specified by any tolerance applicable under Federal law to domestically grown tobacco.

''(2) REVISION OF TOBACCO PRODUCT STANDARDS.—The Secretary may revise the tobacco product standards in paragraph (1) in accordance with subsection (c).

''(3) TOBACCO PRODUCT STANDARDS.—

''(A) IN GENERAL.—The Secretary may adopt tobacco product standards in addition to those in paragraph (1) if the Secretary finds that a tobacco product standard is appropriate for the protection of the public health.

''(B) DETERMINATIONS.—

''(i) CONSIDERATIONS.—In making a finding described in subparagraph (A), the Secretary shall consider scientific evidence concerning—

''(I) the risks and benefits to the population as a whole, including users and nonusers of tobacco products, of the proposed standard;

''(II) the increased or decreased likelihood that existing users of tobacco products will stop using such products; and

''(III) the increased or decreased likelihood that those who do not use tobacco products will start using such products.

''(ii) ADDITIONAL CONSIDERATIONS.—In the event that the Secretary makes a determination, set forth in a proposed tobacco product standard in a proposed rule, that it is appropriate for the protection of public health to require the reduction or elimination of an additive, constituent (including a smoke constituent), or other component of a tobacco product because the Secretary has found that the additive, constituent, or other component is or may be harmful, any party objecting to the proposed standard on the ground that the proposed standard will not reduce or eliminate the risk of illness or injury may provide for the Secretary's consideration scientific evidence that demonstrates that the proposed standard will not reduce or eliminate the risk of illness or injury.

''(4) CONTENT OF TOBACCO PRODUCT STANDARDS.—A tobacco product standard established under this section for a tobacco product—

''(A) shall include provisions that are appropriate for the protection of the public health, including provisions, where appropriate—

''(i) for nicotine yields of the product;

''(ii) for the reduction or elimination of other constituents, including smoke constituents, or harmful components of the product; or

''(iii) relating to any other requirement under subparagraph (B);

''(B) shall, where appropriate for the protection of the public health, include—

''(i) provisions respecting the construction, components, ingredients, additives, constituents, including smoke constituents, and properties of the tobacco product;

''(ii) provisions for the testing (on a sample basis or, if necessary, on an individual basis) of the tobacco product;

''(iii) provisions for the measurement of the tobacco product characteristics of the tobacco product;

''(iv) provisions requiring that the results of each or of certain of the tests of the tobacco product required to be made under clause (ii) show that the tobacco product is in conformity with the portions of the standard for which the test or tests were required; and

''(v) a provision requiring that the sale and distribution of the tobacco product be restricted but only to the extent that the sale and distribution of a tobacco product may be restricted under a regulation under section 906(d);

''(C) shall, where appropriate, require the use and prescribe the form and content of labeling for the proper use of the tobacco product; and

''(D) shall require tobacco products containing foreign-grown tobacco to meet the same standards applicable to tobacco products containing domestically grown tobacco.

''(5) PERIODIC REEVALUATION OF TOBACCO PRODUCT STANDARDS.—The Secretary shall provide for periodic evaluation of tobacco product standards established under this section to determine whether such standards should be changed to reflect new medical, scientific, or other technological data. The Secretary may provide for testing under paragraph (4)(B) by any person.

''(6) INVOLVEMENT OF OTHER AGENCIES; INFORMED PERSONS.—In carrying out duties under this section, the Secretary shall endeavor to—

''(A) use personnel, facilities, and other technical support available in other Federal agencies;

''(B) consult with other Federal agencies concerned with standard setting and other nationally or internationally recognized standard-setting entities; and

''(C) invite appropriate participation, through joint or other conferences, workshops, or other means, by informed persons representative of scientific, professional, industry, agricultural, or consumer organizations who in the Secretary's judgment can make a significant contribution.

''(b) CONSIDERATIONS BY SECRETARY.—

''(1) TECHNICAL ACHIEVABILITY.—The Secretary shall consider information submitted in connection with a proposed standard regarding the technical achievability of compliance with such standard.

''(2) OTHER CONSIDERATIONS.—The Secretary shall consider all other information submitted in connection with a proposed standard, including information concerning the countervailing effects of the tobacco product standard on the health of adolescent tobacco users, adult tobacco users, or nontobacco users, such as the creation of a significant demand for contraband or other tobacco products that do not meet the requirements of this chapter and the significance of such demand.

''(c) PROPOSED STANDARDS.—

''(1) IN GENERAL.—The Secretary shall publish in the Federal Register a notice of proposed rulemaking for the establishment, amendment, or revocation of any tobacco product standard.

''(2) REQUIREMENTS OF NOTICE.—A notice of proposed rulemaking for the establishment or amendment of a tobacco product standard for a tobacco product shall—

''(A) set forth a finding with supporting justification that the tobacco product standard is appropriate for the protection of the public health;

''(B) invite interested persons to submit a draft or proposed tobacco product standard for consideration by the Secretary;

''(C) invite interested persons to submit comments on structuring the standard so that it does not advantage foreign-grown tobacco over domestically grown tobacco; and

''(D) invite the Secretary of Agriculture to provide any information or analysis which the Secretary of Agriculture believes is relevant to the proposed tobacco product standard.

''(3) FINDING.—A notice of proposed rulemaking for the revocation of a tobacco product standard shall set forth a finding with supporting justification that the tobacco product standard is no longer appropriate for the protection of the public health.

''(4) COMMENT.—The Secretary shall provide for a comment period of not less than 60 days.

''(d) PROMULGATION.—

''(1) IN GENERAL.—After the expiration of the period for comment on a notice of proposed rulemaking published under subsection (c) respecting a tobacco product standard and after consideration of comments submitted under subsections (b) and (c) and any report from the Tobacco Products Scientific Advisory Committee, the Secretary shall—

''(A) if the Secretary determines that the standard would be appropriate for the protection of the public health, promulgate a regulation establishing a tobacco product standard and publish in the Federal Register findings on the matters referred to in subsection (c); or

''(B) publish a notice terminating the proceeding for the development of the standard together with the reasons for such termination.

''(2) EFFECTIVE DATE.—A regulation establishing a tobacco product standard shall set forth the date or dates upon which the standard shall take effect, but no such regulation may take effect before 1 year after the date of its publication unless the Secretary determines that an earlier effective date is necessary for the protection of the public health. Such date or dates shall be established so as to minimize, consistent with the public health, economic loss to, and disruption or dislocation of, domestic and international trade. In establishing such effective date or dates, the Secretary shall consider information submitted in connection with a proposed product standard by interested parties, including manufacturers and tobacco growers, regarding the technical achievability of compliance with the standard, and including information concerning the existence of patents that make it impossible to comply in the timeframe envisioned in the proposed standard. If the Secretary determines, based on the Secretary's evaluation of submitted comments, that a product standard can be met only by manufacturers requiring substantial changes to the methods of farming the domestically grown tobacco used by the manufacturer, the effective date of that product standard shall be not less than 2 years after the date of publication of the final regulation establishing the standard.

''(3) LIMITATION ON POWER GRANTED TO THE FOOD AND DRUG ADMINISTRATION.—Because of the importance of a decision of the Secretary to issue a regulation—

''(A) banning all cigarettes, all smokeless tobacco products, all little cigars, all cigars other than little cigars, all pipe tobacco, or all roll-your-own tobacco products; or

''(B) requiring the reduction of nicotine yields of a tobacco product to zero,

the Secretary is prohibited from taking such actions under this Act.

''(4) AMENDMENT; REVOCATION.—

''(A) AUTHORITY.—The Secretary, upon the Secretary's own initiative or upon petition of an interested person, may by a regulation, promulgated in accordance with the requirements of subsection (c) and paragraph (2), amend or revoke a tobacco product standard.

''(B) EFFECTIVE DATE.—The Secretary may declare a proposed amendment of a tobacco product standard to be effective on and after its publication in the Federal Register and until the effective date of any final action taken on such amendment if the Secretary

determines that making it so effective is in the public interest.

''(5) REFERRAL TO ADVISORY COMMITTEE.—

''(A) IN GENERAL.—The Secretary may refer a proposed regulation for the establishment, amendment, or revocation of a tobacco product standard to the Tobacco Products Scientific Advisory Committee for a report and recommendation with respect to any matter involved in the proposed regulation which requires the exercise of scientific judgment.

''(B) INITIATION OF REFERRAL.—The Secretary may make a referral under this paragraph—

''(i) on the Secretary's own initiative; or

''(ii) upon the request of an interested person that—

''(I) demonstrates good cause for the referral; and

''(II) is made before the expiration of the period for submission of comments on the proposed regulation.

''(C) PROVISION OF DATA.—If a proposed regulation is referred under this paragraph to the Tobacco Products Scientific Advisory Committee, the Secretary shall provide the Advisory Committee with the data and information on which such proposed regulation is based.

''(D) REPORT AND RECOMMENDATION.—The Tobacco Products Scientific Advisory Committee shall, within 60 days after the referral of a proposed regulation under this paragraph and after independent study of the data and information furnished to it by the Secretary and other data and information before it, submit to the Secretary a report and recommendation respecting such regulation, together with all underlying data and information and a statement of the reason or basis for the recommendation.

''(E) PUBLIC AVAILABILITY.—The Secretary shall make a copy of each report and recommendation under subparagraph (D) publicly available.

''(e) MENTHOL CIGARETTES.—

''(1) REFERRAL; CONSIDERATIONS.—Immediately upon the establishment of the Tobacco Products Scientific Advisory Committee under section 917(a), the Secretary shall refer to the Committee for report and recommendation, under section 917(c)(4), the issue of the impact of the use of menthol in cigarettes on the public health, including such use among children, African-Americans, Hispanics, and other racial and ethnic minorities. In its review, the Tobacco Products Scientific Advisory Committee shall address the considerations listed in subsections (a)(3)(B)(i) and (b).

''(2) REPORT AND RECOMMENDATION.—Not later than 1 year after its establishment, the Tobacco Product Scientific Advisory Committee shall submit to the Secretary the report and recommendations required pursuant to paragraph (1).

''(3) RULE OF CONSTRUCTION.—Nothing in this subsection shall be construed to limit the Secretary's authority to take action under this section or other sections of this Act applicable to menthol.

''(f) DISSOLVABLE TOBACCO PRODUCTS.—

''(1) REFERRAL; CONSIDERATIONS.—The Secretary shall refer to the Tobacco Products Scientific Advisory Committee for report and recommendation, under section 917(c)(4), the issue of the nature and impact of the use of dissolvable tobacco products on the public health, including such use among children. In its review, the Tobacco Products Scientific Advisory Committee shall address the considerations listed in subsection (a)(3)(B)(i).

''(2) REPORT AND RECOMMENDATION.—Not later than 2 years after its establishment, the Tobacco Product Scientific Advisory Committee shall submit to the Secretary the report and recommendations required pursuant to paragraph (1).

''(3) RULE OF CONSTRUCTION.—Nothing in this subsection shall be construed to limit the Secretary's authority to take action under this section or other sections of this Act at any time applicable to any dissolvable tobacco product.

''SEC. 908. NOTIFICATION AND OTHER REMEDIES.

''(a) NOTIFICATION.—If the Secretary determines that—

''(1) a tobacco product which is introduced or delivered for introduction into interstate commerce for commercial distribution presents an unreasonable risk of substantial harm to the public health; and

''(2) notification under this subsection is necessary to eliminate the unreasonable risk of such harm and no more practicable means is available under the provisions of this chapter (other than this section) to eliminate such risk,

the Secretary may issue such order as may be necessary to assure that adequate notification is provided in an appropriate form, by the persons and means best suited under the circumstances involved, to all persons who should properly receive such notification in order to eliminate such risk. The Secretary may order notification by any appropriate means, including public service announcements. Before issuing an order under this subsection, the Secretary shall consult with the persons who are to give notice under the order.

''(b) NO EXEMPTION FROM OTHER LIABILITY.—Compliance with an order issued under this section shall not relieve any person from liability under Federal or State law. In awarding damages for economic loss in an action brought for the enforcement of any such liability, the value to the plaintiff in such action of any remedy provided under such order shall be taken into account.

''(c) RECALL AUTHORITY.—

''(1) IN GENERAL.—If the Secretary finds that there is a reasonable probability that a tobacco product contains a manufacturing or other defect not ordinarily contained in tobacco products on the market that would cause serious, adverse health consequences or death, the Secretary shall issue an order requiring the appropriate person (including the manufacturers, importers, distributors, or retailers of the tobacco product) to immediately cease distribution of such tobacco product. The order shall provide the person subject to the order with an opportunity for an informal hearing, to be held not later than 10 days after the date of the issuance of the order, on the actions required by the order and on whether the order should be amended to require a recall of such tobacco product. If, after providing an opportunity for such a hearing, the Secretary determines that inadequate grounds exist to support the actions required by the order, the Secretary shall vacate the order.

''(2) AMENDMENT OF ORDER TO REQUIRE RECALL.—

''(A) IN GENERAL.—If, after providing an opportunity for an informal hearing under paragraph (1), the Secretary determines that the order should be amended to include a recall of the tobacco product with respect to which the order was issued, the Secretary shall, except as provided in subparagraph (B), amend the order to require a recall. The Secretary shall specify a timetable in which the tobacco product recall will occur and shall require periodic reports to the Secretary describing the progress of the recall.

''(B) NOTICE.—An amended order under subparagraph (A)—

''(i) shall not include recall of a tobacco product from individuals; and

''(ii) shall provide for notice to persons subject to the risks associated with the use of such tobacco product.

In providing the notice required by clause (ii), the Secretary may use the assistance of retailers and other persons who distributed such tobacco product. If a significant number of such persons cannot be identified, the Secretary shall notify such persons under section 705(b).

''(3) REMEDY NOT EXCLUSIVE.—The remedy provided by this subsection shall be in addition to remedies provided by subsection (a).

''SEC. 909. RECORDS AND REPORTS ON TOBACCO PRODUCTS.

''(a) IN GENERAL.—Every person who is a tobacco product manufacturer or importer of a tobacco product shall establish and maintain such records, make such reports, and provide such information, as the Secretary may by regulation reasonably require to assure that such tobacco product is not adulterated or misbranded and to otherwise protect public health. Regulations prescribed under the preceding sentence—

''(1) may require a tobacco product manufacturer or importer to report to the Secretary whenever the manufacturer or importer receives or otherwise becomes aware of information that reasonably suggests that one of its marketed tobacco products may have caused or contributed to a serious unexpected adverse experience associated with the use of the product or any significant increase in the frequency of a serious, expected adverse product experience;

''(2) shall require reporting of other significant adverse tobacco product experiences as determined by the Secretary to be necessary to be reported;

''(3) shall not impose requirements unduly burdensome to a tobacco product manufacturer or importer, taking into account the cost of complying with such requirements and the need for the protection of the public health and the implementation of this chapter;

''(4) when prescribing the procedure for making requests for reports or information, shall require that each request made under such regulations for submission of a report or information to the Secretary state the reason or purpose for such request and identify to the fullest extent practicable such report or information;

''(5) when requiring submission of a report or information to the Secretary, shall state the reason or purpose for the submission of such report or information and identify to the fullest extent practicable such report or information; and

''(6) may not require that the identity of any patient or user be disclosed in records, reports, or information required under this subsection unless required for the medical welfare of an individual, to determine risks to public health of a tobacco product, or to verify a record, report, or information submitted under this chapter.

In prescribing regulations under this subsection, the Secretary shall have due regard for the professional ethics of the medical profession and the interests of patients. The prohibitions of paragraph (6) continue to apply to records, reports, and information concerning any individual who has been a patient, irrespective of whether or when he ceases to be a patient.

''(b) REPORTS OF REMOVALS AND CORRECTIONS.—

''(1) IN GENERAL.—Except as provided in paragraph (2), the Secretary shall by regulation require a tobacco product manufacturer or importer of a tobacco product to report promptly to the Secretary any corrective action taken or removal from the market of a

tobacco product undertaken by such manufacturer or importer if the removal or correction was undertaken—

''(A) to reduce a risk to health posed by the tobacco product; or

''(B) to remedy a violation of this chapter caused by the tobacco product which may present a risk to health.

A tobacco product manufacturer or importer of a tobacco product who undertakes a corrective action or removal from the market of a tobacco product which is not required to be reported under this subsection shall keep a record of such correction or removal.

''(2) EXCEPTION.—No report of the corrective action or removal of a tobacco product may be required under paragraph (1) if a report of the corrective action or removal is required and has been submitted under subsection (a).

''SEC. 910. APPLICATION FOR REVIEW OF CERTAIN TOBACCO PRODUCTS.

''(a) IN GENERAL.—

''(1) NEW TOBACCO PRODUCT DEFINED.—For purposes of this section the term 'new tobacco product' means—

''(A) any tobacco product (including those products in test markets) that was not commercially marketed in the United States as of February 15, 2007; or

''(B) any modification (including a change in design, any component, any part, or any constituent, including a smoke constituent, or in the content, delivery or form of nicotine, or any other additive or ingredient) of a tobacco product where the modified product was commercially marketed in the United States after February 15, 2007.

''(2) PREMARKET REVIEW REQUIRED.—

''(A) NEW PRODUCTS.—An order under subsection (c)(1)(A)(i) for a new tobacco product is required unless—

''(i) the manufacturer has submitted a report under section 905(j); and the Secretary has issued an order that the tobacco product—

''(I) is substantially equivalent to a tobacco product commercially marketed (other than for test marketing) in the United States as of February 15, 2007; and

''(II) is in compliance with the requirements of this Act; or

''(ii) the tobacco product is exempt from the requirements of section 905(j) pursuant to a regulation issued under section 905(j)(3).

''(B) APPLICATION TO CERTAIN POST-FEBRUARY 15, 2007, PRODUCTS.—Subparagraph (A) shall not apply to a tobacco product—

''(i) that was first introduced or delivered for introduction into interstate commerce for commercial distribution in the United States after February 15, 2007, and prior to the date that is 21 months after the date of enactment of the Family Smoking Prevention and Tobacco Control Act; and

''(ii) for which a report was submitted under section 905(j) within such 21-month period,

except that subparagraph (A) shall apply to the tobacco product if the Secretary issues an order that the tobacco product is not substantially equivalent.

''(3) SUBSTANTIALLY EQUIVALENT DEFINED.—

''(A) IN GENERAL.—In this section and section 905(j), the term 'substantially equivalent' or 'substantial equivalence' means, with respect to the tobacco product being compared to the predicate tobacco product, that the Secretary by order has found that the tobacco product—

''(i) has the same characteristics as the predicate tobacco product; or

''(ii) has different characteristics and the information submitted contains information, including clinical data if deemed necessary by the Secretary, that demonstrates that it is not appropriate to regulate the product under this section because the product does not raise different questions of public health.

''(B) CHARACTERISTICS.—In subparagraph (A), the term 'characteristics' means the materials, ingredients, design, composition, heating source, or other features of a tobacco product.

''(C) LIMITATION.—A tobacco product may not be found to be substantially equivalent to a predicate tobacco product that has been removed from the market at the initiative of the Secretary or that has been determined by a judicial order to be misbranded or adulterated.

''(4) HEALTH INFORMATION.—

''(A) SUMMARY.—As part of a submission under section 905(j) respecting a tobacco product, the person required to file a premarket notification under such section shall provide an adequate summary of any health information related to the tobacco product or state that such information will be made available upon request by any person.

''(B) REQUIRED INFORMATION.—Any summary under subparagraph (A) respecting a tobacco product shall contain detailed information regarding data concerning adverse health effects and shall be made available to the public by the Secretary within 30 days of the issuance of a determination that such tobacco product is substantially equivalent to another tobacco product.

''(b) APPLICATION.—

''(1) CONTENTS.—An application under this section shall contain—

''(A) full reports of all information, published or known to, or which should reasonably be known to, the applicant, concerning investigations which have been made to show the health risks of such tobacco product and whether such tobacco product presents less risk than other tobacco products;

''(B) a full statement of the components, ingredients, additives, and properties, and of the principle or principles of operation, of such tobacco product;

''(C) a full description of the methods used in, and the facilities and controls used for, the manufacture, processing, and, when relevant, packing and installation of, such tobacco product;

''(D) an identifying reference to any tobacco product standard under section 907 which would be applicable to any aspect of such tobacco product, and either adequate information to show that such aspect of such tobacco product fully meets such tobacco product standard or adequate information to justify any deviation from such standard;

''(E) such samples of such tobacco product and of components thereof as the Secretary may reasonably require;

''(F) specimens of the labeling proposed to be used for such tobacco product; and

''(G) such other information relevant to the subject matter of the application as the Secretary may require.

''(2) REFERRAL TO TOBACCO PRODUCTS SCIENTIFIC ADVISORY COMMITTEE.—Upon receipt of an application meeting the requirements set forth in paragraph (1), the Secretary—

''(A) may, on the Secretary's own initiative; or

''(B) may, upon the request of an applicant, refer such application to the Tobacco Products Scientific Advisory Committee for reference and for submission (within such period as the Secretary may establish) of a report and recommendation respecting the application, together with all underlying data and the reasons or basis for the recommendation.

''(c) ACTION ON APPLICATION.—

''(1) DEADLINE.—

''(A) IN GENERAL.—As promptly as possible, but in no event later than 180 days after the receipt of an application under subsection (b), the Secretary, after considering the report and recommendation submitted under subsection (b)(2), shall—

''(i) issue an order that the new product may be introduced or delivered for introduction into interstate commerce if the Secretary finds that none of the grounds specified in paragraph (2) of this subsection applies; or

''(ii) issue an order that the new product may not be introduced or delivered for introduction into interstate commerce if the Secretary finds (and sets forth the basis for such finding as part of or accompanying such denial) that 1 or more grounds for denial specified in paragraph (2) of this subsection apply.

''(B) RESTRICTIONS ON SALE AND DISTRIBUTION.—An order under subparagraph (A)(i) may require that the sale and distribution of the tobacco product be restricted but only to the extent that the sale and distribution of a tobacco product may be restricted under a regulation under section 906(d).

''(2) DENIAL OF APPLICATION.—The Secretary shall deny an application submitted under subsection (b) if, upon the basis of the information submitted to the Secretary as part of the application and any other information before the Secretary with respect to such tobacco product, the Secretary finds that—

''(A) there is a lack of a showing that permitting such tobacco product to be marketed would be appropriate for the protection of the public health;

''(B) the methods used in, or the facilities or controls used for, the manufacture, processing, or packing of such tobacco product do not conform to the requirements of section 906(e);

''(C) based on a fair evaluation of all material facts, the proposed labeling is false or misleading in any particular; or

''(D) such tobacco product is not shown to conform in all respects to a tobacco product standard in effect under section 907, and there is a lack of adequate information to justify the deviation from such standard.

''(3) DENIAL INFORMATION.—Any denial of an application shall, insofar as the Secretary determines to be practicable, be accompanied by a statement informing the applicant of the measures required to remove such application from deniable form (which measures may include further research by the applicant in accordance with 1 or more protocols prescribed by the Secretary).

''(4) BASIS FOR FINDING.—For purposes of this section, the finding as to whether the marketing of a tobacco product for which an application has been submitted is appropriate for the protection of the public health shall be determined with respect to the risks and benefits to the population as a whole, including users and nonusers of the tobacco product, and taking into account—

''(A) the increased or decreased likelihood that existing users of tobacco products will stop using such products; and

''(B) the increased or decreased likelihood that those who do not use tobacco products will start using such products.

''(5) BASIS FOR ACTION.—

''(A) INVESTIGATIONS.—For purposes of paragraph (2)(A), whether permitting a tobacco product to be marketed would be appropriate for the protection of the public health shall, when appropriate, be determined on the basis of well-controlled investigations, which may include 1 or more clinical investigations by experts qualified by training and experience to evaluate the tobacco product.

''(B) OTHER EVIDENCE.—If the Secretary determines that there exists valid scientific evidence (other than evidence derived from investigations described in subparagraph (A)) which is sufficient to evaluate the tobacco product, the Secretary may authorize

that the determination for purposes of paragraph (2)(A) be made on the basis of such evidence.

''(d) WITHDRAWAL AND TEMPORARY SUSPENSION.—

''(1) IN GENERAL.—The Secretary shall, upon obtaining, where appropriate, advice on scientific matters from the Tobacco Products Scientific Advisory Committee, and after due notice and opportunity for informal hearing for a tobacco product for which an order was issued under subsection (c)(1)(A)(i), issue an order withdrawing the order if the Secretary finds—

''(A) that the continued marketing of such tobacco product no longer is appropriate for the protection of the public health;

''(B) that the application contained or was accompanied by an untrue statement of a material fact;

''(C) that the applicant—

''(i) has failed to establish a system for maintaining records, or has repeatedly or deliberately failed to maintain records or to make reports, required by an applicable regulation under section 909;

''(ii) has refused to permit access to, or copying or verification of, such records as required by section 704; or

''(iii) has not complied with the requirements of section 905;

''(D) on the basis of new information before the Secretary with respect to such tobacco product, evaluated together with the evidence before the Secretary when the application was reviewed, that the methods used in, or the facilities and controls used for, the manufacture, processing, packing, or installation of such tobacco product do not conform with the requirements of section 906(e) and were not brought into conformity with such requirements within a reasonable time after receipt of written notice from the Secretary of nonconformity;

''(E) on the basis of new information before the Secretary, evaluated together with the evidence before the Secretary when the application was reviewed, that the labeling of such tobacco product, based on a fair evaluation of all material facts, is false or misleading in any particular and was not corrected within a reasonable time after receipt of written notice from the Secretary of such fact; or

''(F) on the basis of new information before the Secretary, evaluated together with the evidence before the Secretary when such order was issued, that such tobacco product is not shown to conform in all respects to a tobacco product standard which is in effect under section 907, compliance with which was a condition to the issuance of an order relating to the application, and that there is a lack of adequate information to justify the deviation from such standard.

''(2) APPEAL.—The holder of an application subject to an order issued under paragraph (1) withdrawing an order issued pursuant to subsection (c)(1)(A)(i) may, by petition filed on or before the 30th day after the date upon which such holder receives notice of such withdrawal, obtain review thereof in accordance with section 912.

''(3) TEMPORARY SUSPENSION.—If, after providing an opportunity for an informal hearing, the Secretary determines there is reasonable probability that the continuation of distribution of a tobacco product under an order would cause serious, adverse health consequences or death, that is greater than ordinarily caused by tobacco products on the market, the Secretary shall by order temporarily suspend the authority of the manufacturer to market the product. If the Secretary issues such an order, the Secretary shall proceed expeditiously under paragraph (1) to withdraw such application.

''(e) SERVICE OF ORDER.—An order issued by the Secretary under this section shall be served—

''(1) in person by any officer or employee of the department designated by the Secretary; or

''(2) by mailing the order by registered mail or certified mail addressed to the applicant at the applicant's last known address in the records of the Secretary.

''(f) RECORDS.—

''(1) ADDITIONAL INFORMATION.—In the case of any tobacco product for which an order issued pursuant to subsection (c)(1)(A)(i) for an application filed under subsection (b) is in effect, the applicant shall establish and maintain such records, and make such reports to the Secretary, as the Secretary may by regulation, or by order with respect to such application, prescribe on the basis of a finding that such records and reports are necessary in order to enable the Secretary to determine, or facilitate a determination of, whether there is or may be grounds for withdrawing or temporarily suspending such order.

''(2) ACCESS TO RECORDS.—Each person required under this section to maintain records, and each person in charge of custody thereof, shall, upon request of an officer or employee designated by the Secretary, permit such officer or employee at all reasonable times to have access to and copy and verify such records.

''(g) INVESTIGATIONAL TOBACCO PRODUCT EXEMPTION FOR INVESTIGATIONAL USE.—The Secretary may exempt tobacco products intended for investigational use from the provisions of this chapter under such conditions as the Secretary may by regulation prescribe.

''SEC. 911. MODIFIED RISK TOBACCO PRODUCTS.

''(a) IN GENERAL.—No person may introduce or deliver for introduction into interstate commerce any modified risk tobacco product unless an order issued pursuant to subsection (g) is effective with respect to such product.

''(b) DEFINITIONS.—In this section:

''(1) MODIFIED RISK TOBACCO PRODUCT.—The term 'modified risk tobacco product' means any tobacco product that is sold or distributed for use to reduce harm or the risk of tobacco-related disease associated with commercially marketed tobacco products.

''(2) SOLD OR DISTRIBUTED.—

''(A) IN GENERAL.—With respect to a tobacco product, the term 'sold or distributed for use to reduce harm or the risk of tobacco-related disease associated with commercially marketed tobacco products' means a tobacco product—

''(i) the label, labeling, or advertising of which represents explicitly or implicitly that—

''(I) the tobacco product presents a lower risk of tobacco-related disease or is less harmful than one or more other commercially marketed tobacco products;

''(II) the tobacco product or its smoke contains a reduced level of a substance or presents a reduced exposure to a substance; or

''(III) the tobacco product or its smoke does not contain or is free of a substance;

''(ii) the label, labeling, or advertising of which uses the descriptors 'light', 'mild', or 'low' or similar descriptors; or

''(iii) the tobacco product manufacturer of which has taken any action directed to consumers through the media or otherwise, other than by means of the tobacco product's label, labeling, or advertising, after the date of enactment of the Family Smoking Prevention and Tobacco Control Act, respecting the product that would be reasonably expected to result in consumers believing that the tobacco product or its smoke may present a lower risk of disease or is less harmful than one or more commercially marketed tobacco products, or presents a reduced exposure to, or does not contain or is free of, a substance or substances.

''(B) LIMITATION.—No tobacco product shall be considered to be 'sold or distributed for use to reduce harm or the risk of tobacco-related disease associated with commercially marketed tobacco products', except as described in subparagraph (A).

''(C) SMOKELESS TOBACCO PRODUCT.—No smokeless tobacco product shall be considered to be 'sold or distributed for use to reduce harm or the risk of tobacco-related disease associated with commercially marketed tobacco products' solely because its label, labeling, or advertising uses the following phrases to describe such product and its use: 'smokeless tobacco', 'smokeless tobacco product', 'not consumed by smoking', 'does not produce smoke', 'smokefree', 'smoke-free', 'without smoke', 'no smoke', or 'not smoke'.

''(3) EFFECTIVE DATE.—The provisions of paragraph (2)(A)(ii) shall take effect 12 months after the date of enactment of the Family Smoking Prevention and Tobacco Control Act for those products whose label, labeling, or advertising contains the terms described in such paragraph on such date of enactment. The effective date shall be with respect to the date of manufacture, provided that, in any case, beginning 30 days after such effective date, a manufacturer shall not introduce into the domestic commerce of the United States any product, irrespective of the date of manufacture, that is not in conformance with paragraph (2)(A)(ii).

''(c) TOBACCO DEPENDENCE PRODUCTS.—A product that is intended to be used for the treatment of tobacco dependence, including smoking cessation, is not a modified risk tobacco product under this section if it has been approved as a drug or device by the Food and Drug Administration and is subject to the requirements of chapter V.

''(d) FILING.—Any person may file with the Secretary an application for a modified risk tobacco product. Such application shall include—

''(1) a description of the proposed product and any proposed advertising and labeling;

''(2) the conditions for using the product;

''(3) the formulation of the product;

''(4) sample product labels and labeling;

''(5) all documents (including underlying scientific information) relating to research findings conducted, supported, or possessed by the tobacco product manufacturer relating to the effect of the product on tobacco-related diseases and health-related conditions, including information both favorable and unfavorable to the ability of the product to reduce risk or exposure and relating to human health;

''(6) data and information on how consumers actually use the tobacco product; and

''(7) such other information as the Secretary may require.

''(e) PUBLIC AVAILABILITY.—The Secretary shall make the application described in subsection (d) publicly available (except matters in the application which are trade secrets or otherwise confidential, commercial information) and shall request comments by interested persons on the information contained in the application and on the label, labeling, and advertising accompanying such application.

''(f) ADVISORY COMMITTEE.—

''(1) IN GENERAL.—The Secretary shall refer to the Tobacco Products Scientific Advisory Committee any application submitted under this section.

''(2) RECOMMENDATIONS.—Not later than 60 days after the date an application is referred to the Tobacco Products Scientific Advisory

Committee under paragraph (1), the Advisory Committee shall report its recommendations on the application to the Secretary.

''(g) MARKETING.—

''(1) MODIFIED RISK PRODUCTS.—Except as provided in paragraph (2), the Secretary shall, with respect to an application submitted under this section, issue an order that a modified risk product may be commercially marketed only if the Secretary determines that the applicant has demonstrated that such product, as it is actually used by consumers, will—

''(A) significantly reduce harm and the risk of tobacco-related disease to individual tobacco users; and

''(B) benefit the health of the population as a whole taking into account both users of tobacco products and persons who do not currently use tobacco products.

''(2) SPECIAL RULE FOR CERTAIN PRODUCTS.—

''(A) IN GENERAL.—The Secretary may issue an order that a tobacco product may be introduced or delivered for introduction into interstate commerce, pursuant to an application under this section, with respect to a tobacco product that may not be commercially marketed under paragraph (1) if the Secretary makes the findings required under this paragraph and determines that the applicant has demonstrated that—

''(i) such order would be appropriate to promote the public health;

''(ii) any aspect of the label, labeling, and advertising for such product that would cause the tobacco product to be a modified risk tobacco product under subsection (b) is limited to an explicit or implicit representation that such tobacco product or its smoke does not contain or is free of a substance or contains a reduced level of a substance, or presents a reduced exposure to a substance in tobacco smoke;

''(iii) scientific evidence is not available and, using the best available scientific methods, cannot be made available without conducting long-term epidemiological studies for an application to meet the standards set forth in paragraph (1); and

''(iv) the scientific evidence that is available without conducting long-term epidemiological studies demonstrates that a measurable and substantial reduction in morbidity or mortality among individual tobacco users is reasonably likely in subsequent studies.

''(B) ADDITIONAL FINDINGS REQUIRED.—To issue an order under subparagraph (A) the Secretary must also find that the applicant has demonstrated that—

''(i) the magnitude of the overall reductions in exposure to the substance or substances which are the subject of the application is substantial, such substance or substances are harmful, and the product as actually used exposes consumers to the specified reduced level of the substance or substances;

''(ii) the product as actually used by consumers will not expose them to higher levels of other harmful substances compared to the similar types of tobacco products then on the market unless such increases are minimal and the reasonably likely overall impact of use of the product remains a substantial and measurable reduction in overall morbidity and mortality among individual tobacco users;

''(iii) testing of actual consumer perception shows that, as the applicant proposes to label and market the product, consumers will not be misled into believing that the product—

''(I) is or has been demonstrated to be less harmful; or

''(II) presents or has been demonstrated to present less of a risk of disease than 1 or more other commercially marketed tobacco products; and

''(iv) issuance of an order with respect to the application is expected to benefit the health of the population as a whole taking into account both users of tobacco products and persons who do not currently use tobacco products.

''(C) CONDITIONS OF MARKETING.—

''(i) IN GENERAL.—Applications subject to an order under this paragraph shall be limited to a term of not more than 5 years, but may be renewed upon a finding by the Secretary that the requirements of this paragraph continue to be satisfied based on the filing of a new application.

''(ii) AGREEMENTS BY APPLICANT.—An order under this paragraph shall be conditioned on the applicant's agreement to conduct postmarket surveillance and studies and to submit to the Secretary the results of such surveillance and studies to determine the impact of the order on consumer perception, behavior, and health and to enable the Secretary to review the accuracy of the determinations upon which the order was based in accordance with a protocol approved by the Secretary.

''(iii) ANNUAL SUBMISSION.—The results of such postmarket surveillance and studies described in clause (ii) shall be submitted annually.

''(3) BASIS.—The determinations under paragraphs (1) and (2) shall be based on—

''(A) the scientific evidence submitted by the applicant; and

''(B) scientific evidence and other information that is made available to the Secretary.

''(4) BENEFIT TO HEALTH OF INDIVIDUALS AND OF POPULATION AS A WHOLE.—In making the determinations under paragraphs (1) and (2), the Secretary shall take into account—

''(A) the relative health risks to individuals of the tobacco product that is the subject of the application;

''(B) the increased or decreased likelihood that existing users of tobacco products who would otherwise stop using such products will switch to the tobacco product that is the subject of the application;

''(C) the increased or decreased likelihood that persons who do not use tobacco products will start using the tobacco product that is the subject of the application;

''(D) the risks and benefits to persons from the use of the tobacco product that is the subject of the application as compared to the use of products for smoking cessation approved under chapter V to treat nicotine dependence; and

''(E) comments, data, and information submitted by interested persons.

''(h) ADDITIONAL CONDITIONS FOR MARKETING.—

''(1) MODIFIED RISK PRODUCTS.—The Secretary shall require for the marketing of a product under this section that any advertising or labeling concerning modified risk products enable the public to comprehend the information concerning modified risk and to understand the relative significance of such information in the context of total health and in relation to all of the diseases and health-related conditions associated with the use of tobacco products.

''(2) COMPARATIVE CLAIMS.—

''(A) IN GENERAL.—The Secretary may require for the marketing of a product under this subsection that a claim comparing a tobacco product to 1 or more other commercially marketed tobacco products shall compare the tobacco product to a commercially marketed tobacco product that is representative of that type of tobacco product on the market (for example the average value of the top 3 brands of an established regular tobacco product).

''(B) QUANTITATIVE COMPARISONS.—The Secretary may also require, for purposes of subparagraph (A), that the percent (or fraction) of change and identity of the reference tobacco product and a quantitative comparison of the amount of the substance claimed to be reduced shall be stated in immediate proximity to the most prominent claim.

''(3) LABEL DISCLOSURE.—

''(A) IN GENERAL.—The Secretary may require the disclosure on the label of other substances in the tobacco product, or substances that may be produced by the consumption of that tobacco product, that may affect a disease or health-related condition or may increase the risk of other diseases or health-related conditions associated with the use of tobacco products.

''(B) CONDITIONS OF USE.—If the conditions of use of the tobacco product may affect the risk of the product to human health, the Secretary may require the labeling of conditions of use.

''(4) TIME.—An order issued under subsection (g)(1) shall be effective for a specified period of time.

''(5) ADVERTISING.—The Secretary may require, with respect to a product for which an applicant obtained an order under subsection (g)(1), that the product comply with requirements relating to advertising and promotion of the tobacco product.

''(i) POSTMARKET SURVEILLANCE AND STUDIES.—

''(1) IN GENERAL.—The Secretary shall require, with respect to a product for which an applicant obtained an order under subsection (g)(1), that the applicant conduct postmarket surveillance and studies for such a tobacco product to determine the impact of the order issuance on consumer perception, behavior, and health, to enable the Secretary to review the accuracy of the determinations upon which the order was based, and to provide information that the Secretary determines is otherwise necessary regarding the use or health risks involving the tobacco product. The results of postmarket surveillance and studies shall be submitted to the Secretary on an annual basis.

''(2) SURVEILLANCE PROTOCOL.—Each applicant required to conduct a surveillance of a tobacco product under paragraph (1) shall, within 30 days after receiving notice that the applicant is required to conduct such surveillance, submit, for the approval of the Secretary, a protocol for the required surveillance. The Secretary, within 60 days of the receipt of such protocol, shall determine if the principal investigator proposed to be used in the surveillance has sufficient qualifications and experience to conduct such surveillance and if such protocol will result in collection of the data or other information designated by the Secretary as necessary to protect the public health.

''(j) WITHDRAWAL OF AUTHORIZATION.—The Secretary, after an opportunity for an informal hearing, shall withdraw an order under subsection (g) if the Secretary determines that—

''(1) the applicant, based on new information, can no longer make the demonstrations required under subsection (g), or the Secretary can no longer make the determinations required under subsection (g);

''(2) the application failed to include material information or included any untrue statement of material fact;

''(3) any explicit or implicit representation that the product reduces risk or exposure is no longer valid, including if—

''(A) a tobacco product standard is established pursuant to section 907;

''(B) an action is taken that affects the risks presented by other commercially marketed tobacco products that were compared to the product that is the subject of the application; or

''(C) any postmarket surveillance or studies reveal that the order is no longer consistent with the protection of the public health;

''(4) the applicant failed to conduct or submit the postmarket surveillance and studies required under subsection (g)(2)(C)(ii) or subsection (i); or

''(5) the applicant failed to meet a condition imposed under subsection (h).

''(k) CHAPTER IV OR V.—A product for which the Secretary has issued an order pursuant to subsection (g) shall not be subject to chapter IV or V.

''(l) IMPLEMENTING REGULATIONS OR GUIDANCE.—

''(1) SCIENTIFIC EVIDENCE.—Not later than 2 years after the date of enactment of the Family Smoking Prevention and Tobacco Control Act, the Secretary shall issue regulations or guidance (or any combination thereof) on the scientific evidence required for assessment and ongoing review of modified risk tobacco products. Such regulations or guidance shall—

''(A) to the extent that adequate scientific evidence exists, establish minimum standards for scientific studies needed prior to issuing an order under subsection (g) to show that a substantial reduction in morbidity or mortality among individual tobacco users occurs for products described in subsection (g)(1) or is reasonably likely for products described in subsection (g)(2);

''(B) include validated biomarkers, intermediate clinical endpoints, and other feasible outcome measures, as appropriate;

''(C) establish minimum standards for postmarket studies, that shall include regular and long-term assessments of health outcomes and mortality, intermediate clinical endpoints, consumer perception of harm reduction, and the impact on quitting behavior and new use of tobacco products, as appropriate;

''(D) establish minimum standards for required postmarket surveillance, including ongoing assessments of consumer perception;

''(E) require that data from the required studies and surveillance be made available to the Secretary prior to the decision on renewal of a modified risk tobacco product; and

''(F) establish a reasonable timetable for the Secretary to review an application under this section.

''(2) CONSULTATION.—The regulations or guidance issued under paragraph (1) shall be developed in consultation with the Institute of Medicine, and with the input of other appropriate scientific and medical experts, on the design and conduct of such studies and surveillance.

''(3) REVISION.—The regulations or guidance under paragraph (1) shall be revised on a regular basis as new scientific information becomes available.

''(4) NEW TOBACCO PRODUCTS.—Not later than 2 years after the date of enactment of the Family Smoking Prevention and Tobacco Control Act, the Secretary shall issue a regulation or guidance that permits the filing of a single application for any tobacco product that is a new tobacco product under section 910 and which the applicant seeks to commercially market under this section.

''(m) DISTRIBUTORS.—Except as provided in this section, no distributor may take any action, after the date of enactment of the Family Smoking Prevention and Tobacco Control Act, with respect to a tobacco product that would reasonably be expected to result in consumers believing that the tobacco product or its smoke may present a lower risk of disease or is less harmful than one or more commercially marketed tobacco products, or presents a reduced exposure to, or does not contain or is free of, a substance or substances.

''SEC. 912. JUDICIAL REVIEW.

''(a) RIGHT TO REVIEW.—

''(1) IN GENERAL.—Not later than 30 days after—

''(A) the promulgation of a regulation under section 907 establishing, amending, or revoking a tobacco product standard; or

''(B) a denial of an application under section 910(c),

any person adversely affected by such regulation or denial may file a petition for judicial review of such regulation or denial with the United States Court of Appeals for the District of Columbia or for the circuit in which such person resides or has their principal place of business.

''(2) REQUIREMENTS.—

''(A) COPY OF PETITION.—A copy of the petition filed under paragraph (1) shall be transmitted by the clerk of the court involved to the Secretary.

''(B) RECORD OF PROCEEDINGS.—On receipt of a petition under subparagraph (A), the Secretary shall file in the court in which such petition was filed—

''(i) the record of the proceedings on which the regulation or order was based; and

''(ii) a statement of the reasons for the issuance of such a regulation or order.

''(C) DEFINITION OF RECORD.—In this section, the term 'record' means—

''(i) all notices and other matter published in the Federal Register with respect to the regulation or order reviewed;

''(ii) all information submitted to the Secretary with respect to such regulation or order;

''(iii) proceedings of any panel or advisory committee with respect to such regulation or order;

''(iv) any hearing held with respect to such regulation or order; and

''(v) any other information identified by the Secretary, in the administrative proceeding held with respect to such regulation or order, as being relevant to such regulation or order.

''(b) STANDARD OF REVIEW.—Upon the filing of the petition under subsection (a) for judicial review of a regulation or order, the court shall have jurisdiction to review the regulation or order in accordance with chapter 7 of title 5, United States Code, and to grant appropriate relief, including interim relief, as provided for in such chapter. A regulation or denial described in subsection (a) shall be reviewed in accordance with section 706(2)(A) of title 5, United States Code.

''(c) FINALITY OF JUDGMENT.—The judgment of the court affirming or setting aside, in whole or in part, any regulation or order shall be final, subject to review by the Supreme Court of the United States upon certiorari or certification, as provided in section 1254 of title 28, United States Code.

''(d) OTHER REMEDIES.—The remedies provided for in this section shall be in addition to, and not in lieu of, any other remedies provided by law.

''(e) REGULATIONS AND ORDERS MUST RECITE BASIS IN RECORD.—To facilitate judicial review, a regulation or order issued under section 906, 907, 908, 909, 910, or 916 shall contain a statement of the reasons for the issuance of such regulation or order in the record of the proceedings held in connection with its issuance.

''SEC. 913. EQUAL TREATMENT OF RETAIL OUTLETS.

''The Secretary shall issue regulations to require that retail establishments for which the predominant business is the sale of tobacco products comply with any advertising restrictions applicable to retail establishments accessible to individuals under the age of 18.

''SEC. 914. JURISDICTION OF AND COORDINATION WITH THE FEDERAL TRADE COMMISSION.

''(a) JURISDICTION.—

''(1) IN GENERAL.—Except where expressly provided in this chapter, nothing in this chapter shall be construed as limiting or diminishing the authority of the Federal Trade Commission to enforce the laws under its jurisdiction with respect to the advertising, sale, or distribution of tobacco products.

''(2) ENFORCEMENT.—Any advertising that violates this chapter or a provision of the regulations referred to in section 102 of the Family Smoking Prevention and Tobacco Control Act, is an unfair or deceptive act or practice under section 5(a) of the Federal Trade Commission Act and shall be considered a violation of a rule promulgated under section 18 of that Act.

''(b) COORDINATION.—With respect to the requirements of section 4 of the Federal Cigarette Labeling and Advertising Act and section 3 of the Comprehensive Smokeless Tobacco Health Education Act of 1986—

''(1) the Chairman of the Federal Trade Commission shall coordinate with the Secretary concerning the enforcement of such Act as such enforcement relates to unfair or deceptive acts or practices in the advertising of cigarettes or smokeless tobacco; and

''(2) the Secretary shall consult with the Chairman of such Commission in revising the label statements and requirements under such sections.

''SEC. 915. REGULATION REQUIREMENT.

''(a) TESTING, REPORTING, AND DISCLOSURE.—Not later than 36 months after the date of enactment of the Family Smoking Prevention and Tobacco Control Act, the Secretary shall promulgate regulations under this Act that meet the requirements of subsection (b).

''(b) CONTENTS OF RULES.—The regulations promulgated under subsection (a)—

''(1) shall require testing and reporting of tobacco product constituents, ingredients, and additives, including smoke constituents, by brand and subbrand that the Secretary determines should be tested to protect the public health, provided that, for purposes of the testing requirements of this paragraph, tobacco products manufactured and sold by a single tobacco product manufacturer that are identical in all respects except the labels, packaging design, logo, trade dress, trademark, brand name, or any combination thereof, shall be considered as a single brand; and

''(2) may require that tobacco product manufacturers, packagers, or importers make disclosures relating to the results of the testing of tar and nicotine through labels or advertising or other appropriate means, and make disclosures regarding the results of the testing of other constituents, including smoke constituents, ingredients, or additives, that the Secretary determines should be disclosed to the public to protect the public health and will not mislead consumers about the risk of tobacco-related disease.

''(c) AUTHORITY.—The Secretary shall have the authority under this chapter to conduct or to require the testing, reporting, or disclosure of tobacco product constituents, including smoke constituents.

''(d) SMALL TOBACCO PRODUCT MANUFACTURERS.—

''(1) FIRST COMPLIANCE DATE.—The initial regulations promulgated under subsection (a) shall not impose requirements on small tobacco product manufacturers before the later of—

''(A) the end of the 2-year period following the final promulgation of such regulations; and

''(B) the initial date set by the Secretary for compliance with such regulations by

manufacturers that are not small tobacco product manufacturers.

''(2) TESTING AND REPORTING INITIAL COMPLIANCE PERIOD.—

''(A) 4-YEAR PERIOD.—The initial regulations promulgated under subsection (a) shall give each small tobacco product manufacturer a 4-year period over which to conduct testing and reporting for all of its tobacco products. Subject to paragraph (1), the end of the first year of such 4-year period shall coincide with the initial date of compliance under this section set by the Secretary with respect to manufacturers that are not small tobacco product manufacturers or the end of the 2-year period following the final promulgation of such regulations, as described in paragraph (1)(A). A small tobacco product manufacturer shall be required—

''(i) to conduct such testing and reporting for 25 percent of its tobacco products during each year of such 4-year period; and

''(ii) to conduct such testing and reporting for its largest-selling tobacco products (as determined by the Secretary) before its other tobacco products, or in such other order of priority as determined by the Secretary.

''(B) CASE-BY-CASE DELAY.—Notwithstanding subparagraph (A), the Secretary may, on a case-by-case basis, delay the date by which an individual small tobacco product manufacturer must conduct testing and reporting for its tobacco products under this section based upon a showing of undue hardship to such manufacturer. Notwithstanding the preceding sentence, the Secretary shall not extend the deadline for a small tobacco product manufacturer to conduct testing and reporting for all of its tobacco products beyond a total of 5 years after the initial date of compliance under this section set by the Secretary with respect to manufacturers that are not small tobacco product manufacturers.

''(3) SUBSEQUENT AND ADDITIONAL TESTING AND REPORTING.—The regulations promulgated under subsection (a) shall provide that, with respect to any subsequent or additional testing and reporting of tobacco products required under this section, such testing and reporting by a small tobacco product manufacturer shall be conducted in accordance with the timeframes described in paragraph (2)(A), except that, in the case of a new product, or if there has been a modification described in section 910(a)(1)(B) of any product of a small tobacco product manufacturer since the last testing and reporting required under this section, the Secretary shall require that any subsequent or additional testing and reporting be conducted in accordance with the same timeframe applicable to manufacturers that are not small tobacco product manufacturers.

''(4) JOINT LABORATORY TESTING SERVICES.—The Secretary shall allow any 2 or more small tobacco product manufacturers to join together to purchase laboratory testing services required by this section on a group basis in order to ensure that such manufacturers receive access to, and fair pricing of, such testing services.

''(e) EXTENSIONS FOR LIMITED LABORATORY CAPACITY.—

''(1) IN GENERAL.—The regulations promulgated under subsection (a) shall provide that a small tobacco product manufacturer shall not be considered to be in violation of this section before the deadline applicable under paragraphs (3) and (4), if—

''(A) the tobacco products of such manufacturer are in compliance with all other requirements of this chapter; and

''(B) the conditions described in paragraph (2) are met.

''(2) CONDITIONS.—Notwithstanding the requirements of this section, the Secretary may delay the date by which a small tobacco product manufacturer must be in compliance with the testing and reporting required by this section until such time as the testing is reported if, not later than 90 days before the deadline for reporting in accordance with this section, a small tobacco product manufacturer provides evidence to the Secretary demonstrating that—

''(A) the manufacturer has submitted the required products for testing to a laboratory and has done so sufficiently in advance of the deadline to create a reasonable expectation of completion by the deadline;

''(B) the products currently are awaiting testing by the laboratory; and

''(C) neither that laboratory nor any other laboratory is able to complete testing by the deadline at customary, nonexpedited testing fees.

''(3) EXTENSION.—The Secretary, taking into account the laboratory testing capacity that is available to tobacco product manufacturers, shall review and verify the evidence submitted by a small tobacco product manufacturer in accordance with paragraph (2). If the Secretary finds that the conditions described in such paragraph are met, the Secretary shall notify the small tobacco product manufacturer that the manufacturer shall not be considered to be in violation of the testing and reporting requirements of this section until the testing is reported or until 1 year after the reporting deadline has passed, whichever occurs sooner. If, however, the Secretary has not made a finding before the reporting deadline, the manufacturer shall not be considered to be in violation of such requirements until the Secretary finds that the conditions described in paragraph (2) have not been met, or until 1 year after the reporting deadline, whichever occurs sooner.

''(4) ADDITIONAL EXTENSION.—In addition to the time that may be provided under paragraph (3), the Secretary may provide further extensions of time, in increments of no more than 1 year, for required testing and reporting to occur if the Secretary determines, based on evidence properly and timely submitted by a small tobacco product manufacturer in accordance with paragraph (2), that a lack of available laboratory capacity prevents the manufacturer from completing the required testing during the period described in paragraph (3).

''(f) RULE OF CONSTRUCTION.—Nothing in subsection (d) or (e) shall be construed to authorize the extension of any deadline, or to otherwise affect any timeframe, under any provision of this Act or the Family Smoking Prevention and Tobacco Control Act other than this section.

''SEC. 916. PRESERVATION OF STATE AND LOCAL AUTHORITY.

''(a) IN GENERAL.—

''(1) PRESERVATION.—Except as provided in paragraph (2)(A), nothing in this chapter, or rules promulgated under this chapter, shall be construed to limit the authority of a Federal agency (including the Armed Forces), a State or political subdivision of a State, or the government of an Indian tribe to enact, adopt, promulgate, and enforce any law, rule, regulation, or other measure with respect to tobacco products that is in addition to, or more stringent than, requirements established under this chapter, including a law, rule, regulation, or other measure relating to or prohibiting the sale, distribution, possession, exposure to, access to, advertising and promotion of, or use of tobacco products by individuals of any age, information reporting to the State, or measures relating to fire safety standards for tobacco products. No provision of this chapter shall limit or otherwise affect any State, tribal, or local taxation of tobacco products.

''(2) PREEMPTION OF CERTAIN STATE AND LOCAL REQUIREMENTS.—

''(A) IN GENERAL.—No State or political subdivision of a State may establish or continue in effect with respect to a tobacco product any requirement which is different from, or in addition to, any requirement under the provisions of this chapter relating to tobacco product standards, premarket review, adulteration, misbranding, labeling, registration, good manufacturing standards, or modified risk tobacco products.

''(B) EXCEPTION.—Subparagraph (A) does not apply to requirements relating to the sale, distribution, possession, information reporting to the State, exposure to, access to, the advertising and promotion of, or use of, tobacco products by individuals of any age, or relating to fire safety standards for tobacco products. Information disclosed to a State under subparagraph (A) that is exempt from disclosure under section 552(b)(4) of title 5, United States Code, shall be treated as a trade secret and confidential information by the State.

''(b) RULE OF CONSTRUCTION REGARDING PRODUCT LIABILITY.—No provision of this chapter relating to a tobacco product shall be construed to modify or otherwise affect any action or the liability of any person under the product liability law of any State.

''SEC. 917. TOBACCO PRODUCTS SCIENTIFIC ADVISORY COMMITTEE.

''(a) ESTABLISHMENT.—Not later than 6 months after the date of enactment of the Family Smoking Prevention and Tobacco Control Act, the Secretary shall establish a 12-member advisory committee, to be known as the Tobacco Products Scientific Advisory Committee (in this section referred to as the 'Advisory Committee').

''(b) MEMBERSHIP.—

''(1) IN GENERAL.—

''(A) MEMBERS.—The Secretary shall appoint as members of the Tobacco Products Scientific Advisory Committee individuals who are technically qualified by training and experience in medicine, medical ethics, science, or technology involving the manufacture, evaluation, or use of tobacco products, who are of appropriately diversified professional backgrounds. The committee shall be composed of—

''(i) 7 individuals who are physicians, dentists, scientists, or health care professionals practicing in the area of oncology, pulmonology, cardiology, toxicology, pharmacology, addiction, or any other relevant specialty;

''(ii) 1 individual who is an officer or employee of a State or local government or of the Federal Government;

''(iii) 1 individual as a representative of the general public;

''(iv) 1 individual as a representative of the interests of the tobacco manufacturing industry;

''(v) 1 individual as a representative of the interests of the small business tobacco manufacturing industry, which position may be filled on a rotating, sequential basis by representatives of different small business tobacco manufacturers based on areas of expertise relevant to the topics being considered by the Advisory Committee; and

''(vi) 1 individual as a representative of the interests of the tobacco growers.

''(B) NONVOTING MEMBERS.—The members of the committee appointed under clauses (iv), (v), and (vi) of subparagraph (A) shall serve as consultants to those described in clauses (i) through (iii) of subparagraph (A) and shall be nonvoting representatives.

''(C) CONFLICTS OF INTEREST.—No members of the committee, other than members appointed pursuant to clauses (iv), (v), and (vi) of subparagraph (A) shall, during the member's tenure on the committee or for the 18-

month period prior to becoming such a member, receive any salary, grants, or other payments or support from any business that manufactures, distributes, markets, or sells cigarettes or other tobacco products.

''(2) LIMITATION.—The Secretary may not appoint to the Advisory Committee any individual who is in the regular full-time employ of the Food and Drug Administration or any agency responsible for the enforcement of this Act. The Secretary may appoint Federal officials as ex officio members.

''(3) CHAIRPERSON.—The Secretary shall designate 1 of the members appointed under clauses (i), (ii), and (iii) of paragraph (1)(A) to serve as chairperson.

''(c) DUTIES.—The Tobacco Products Scientific Advisory Committee shall provide advice, information, and recommendations to the Secretary—

''(1) as provided in this chapter;

''(2) on the effects of the alteration of the nicotine yields from tobacco products;

''(3) on whether there is a threshold level below which nicotine yields do not produce dependence on the tobacco product involved; and

''(4) on its review of other safety, dependence, or health issues relating to tobacco products as requested by the Secretary.

''(d) COMPENSATION; SUPPORT; FACA.—

''(1) COMPENSATION AND TRAVEL.—Members of the Advisory Committee who are not officers or employees of the United States, while attending conferences or meetings of the committee or otherwise engaged in its business, shall be entitled to receive compensation at rates to be fixed by the Secretary, which may not exceed the daily equivalent of the rate in effect under the Senior Executive Schedule under section 5382 of title 5, United States Code, for each day (including travel time) they are so engaged; and while so serving away from their homes or regular places of business each member may be allowed travel expenses, including per diem in lieu of subsistence, as authorized by section 5703 of title 5, United States Code, for persons in the Government service employed intermittently.

''(2) ADMINISTRATIVE SUPPORT.—The Secretary shall furnish the Advisory Committee clerical and other assistance.

''(3) NONAPPLICATION OF FACA.—Section 14 of the Federal Advisory Committee Act does not apply to the Advisory Committee.

''(e) PROCEEDINGS OF ADVISORY PANELS AND COMMITTEES.—The Advisory Committee shall make and maintain a transcript of any proceeding of the panel or committee. Each such panel and committee shall delete from any transcript made under this subsection information which is exempt from disclosure under section 552(b) of title 5, United States Code.

''SEC. 918. DRUG PRODUCTS USED TO TREAT TOBACCO DEPENDENCE.

''(a) IN GENERAL.—The Secretary shall—

''(1) at the request of the applicant, consider designating products for smoking cessation, including nicotine replacement products as fast track research and approval products within the meaning of section 506;

''(2) consider approving the extended use of nicotine replacement products (such as nicotine patches, nicotine gum, and nicotine lozenges) for the treatment of tobacco dependence; and

''(3) review and consider the evidence for additional indications for nicotine replacement products, such as for craving relief or relapse prevention.

''(b) REPORT ON INNOVATIVE PRODUCTS.—

''(1) IN GENERAL.—Not later than 3 years after the date of enactment of the Family Smoking Prevention and Tobacco Control Act, the Secretary, after consultation with recognized scientific, medical, and public health experts (including both Federal agencies and nongovernmental entities, the Institute of Medicine of the National Academy of Sciences, and the Society for Research on Nicotine and Tobacco), shall submit to the Congress a report that examines how best to regulate, promote, and encourage the development of innovative products and treatments (including nicotine-based and non-nicotine-based products and treatments) to better achieve, in a manner that best protects and promotes the public health—

''(A) total abstinence from tobacco use;

''(B) reductions in consumption of tobacco; and

''(C) reductions in the harm associated with continued tobacco use.

''(2) RECOMMENDATIONS.—The report under paragraph (1) shall include the recommendations of the Secretary on how the Food and Drug Administration should coordinate and facilitate the exchange of information on such innovative products and treatments among relevant offices and centers within the Administration and within the National Institutes of Health, the Centers for Disease Control and Prevention, and other relevant agencies.

''SEC. 919. USER FEES.

''(a) ESTABLISHMENT OF QUARTERLY FEE.—Beginning on the date of enactment of the Family Smoking Prevention and Tobacco Control Act, the Secretary shall in accordance with this section assess user fees on, and collect such fees from, each manufacturer and importer of tobacco products subject to this chapter. The fees shall be assessed and collected with respect to each quarter of each fiscal year, and the total amount assessed and collected for a fiscal year shall be the amount specified in subsection (b)(1) for such year, subject to subsection (c).

''(b) ASSESSMENT OF USER FEE.—

''(1) AMOUNT OF ASSESSMENT.—The total amount of user fees authorized to be assessed and collected under subsection (a) for a fiscal year is the following, as applicable to the fiscal year involved:

''(A) For fiscal year 2009, $85,000,000 (subject to subsection (e)).

''(B) For fiscal year 2010, $235,000,000.

''(C) For fiscal year 2011, $450,000,000.

''(D) For fiscal year 2012, $477,000,000.

''(E) For fiscal year 2013, $505,000,000.

''(F) For fiscal year 2014, $534,000,000.

''(G) For fiscal year 2015, $566,000,000.

''(H) For fiscal year 2016, $599,000,000.

''(I) For fiscal year 2017, $635,000,000.

''(J) For fiscal year 2018, $672,000,000.

''(K) For fiscal year 2019 and each subsequent fiscal year, $712,000,000.

''(2) ALLOCATIONS OF ASSESSMENT BY CLASS OF TOBACCO PRODUCTS.—

''(A) IN GENERAL.—The total user fees assessed and collected under subsection (a) each fiscal year with respect to each class of tobacco products shall be an amount that is equal to the applicable percentage of each class for the fiscal year multiplied by the amount specified in paragraph (1) for the fiscal year.

''(B) APPLICABLE PERCENTAGE.—

''(i) IN GENERAL.—For purposes of subparagraph (A), the applicable percentage for a fiscal year for each of the following classes of tobacco products shall be determined in accordance with clause (ii):

''(I) Cigarettes.

''(II) Cigars, including small cigars and cigars other than small cigars.

''(III) Snuff.

''(IV) Chewing tobacco.

''(V) Pipe tobacco.

''(VI) Roll-your-own tobacco.

''(ii) ALLOCATIONS.—The applicable percentage of each class of tobacco product described in clause (i) for a fiscal year shall be the percentage determined under section 625(c) of Public Law 108–357 for each such class of product for such fiscal year.

''(iii) REQUIREMENT OF REGULATIONS.—Notwithstanding clause (ii), no user fees shall be assessed on a class of tobacco products unless such class of tobacco products is listed in section 901(b) or is deemed by the Secretary in a regulation under section 901(b) to be subject to this chapter.

''(iv) REALLOCATIONS.—In the case of a class of tobacco products that is not listed in section 901(b) or deemed by the Secretary in a regulation under section 901(b) to be subject to this chapter, the amount of user fees that would otherwise be assessed to such class of tobacco products shall be reallocated to the classes of tobacco products that are subject to this chapter in the same manner and based on the same relative percentages otherwise determined under clause (ii).

''(3) DETERMINATION OF USER FEE BY COMPANY.—

''(A) IN GENERAL.—The total user fee to be paid by each manufacturer or importer of a particular class of tobacco products shall be determined for each quarter by multiplying—

''(i) such manufacturer's or importer's percentage share as determined under paragraph (4); by

''(ii) the portion of the user fee amount for the current quarter to be assessed on all manufacturers and importers of such class of tobacco products as determined under paragraph (2).

''(B) NO FEE IN EXCESS OF PERCENTAGE SHARE.—No manufacturer or importer of tobacco products shall be required to pay a user fee in excess of the percentage share of such manufacturer or importer.

''(4) ALLOCATION OF ASSESSMENT WITHIN EACH CLASS OF TOBACCO PRODUCT.—The percentage share of each manufacturer or importer of a particular class of tobacco products of the total user fee to be paid by all manufacturers or importers of that class of tobacco products shall be the percentage determined for purposes of allocations under subsections (e) through (h) of section 625 of Public Law 108–357.

''(5) ALLOCATION FOR CIGARS.—Notwithstanding paragraph (4), if a user fee assessment is imposed on cigars, the percentage share of each manufacturer or importer of cigars shall be based on the excise taxes paid by such manufacturer or importer during the prior fiscal year.

''(6) TIMING OF ASSESSMENT.—The Secretary shall notify each manufacturer and importer of tobacco products subject to this section of the amount of the quarterly assessment imposed on such manufacturer or importer under this subsection for each quarter of each fiscal year. Such notifications shall occur not later than 30 days prior to the end of the quarter for which such assessment is made, and payments of all assessments shall be made by the last day of the quarter involved.

''(7) MEMORANDUM OF UNDERSTANDING.—

''(A) IN GENERAL.—The Secretary shall request the appropriate Federal agency to enter into a memorandum of understanding that provides for the regular and timely transfer from the head of such agency to the Secretary of the information described in paragraphs (2)(B)(ii) and (4) and all necessary information regarding all tobacco product manufacturers and importers required to pay user fees. The Secretary shall maintain all disclosure restrictions established by the head of such agency regarding the information provided under the memorandum of understanding.

''(B) ASSURANCES.—Beginning not later than fiscal year 2015, and for each subsequent

fiscal year, the Secretary shall ensure that the Food and Drug Administration is able to determine the applicable percentages described in paragraph (2) and the percentage shares described in paragraph (4). The Secretary may carry out this subparagraph by entering into a contract with the head of the Federal agency referred to in subparagraph (A) to continue to provide the necessary information.

''(c) CREDITING AND AVAILABILITY OF FEES.—

''(1) IN GENERAL.—Fees authorized under subsection (a) shall be collected and available for obligation only to the extent and in the amount provided in advance in appropriations Acts, subject to paragraph (2)(D). Such fees are authorized to remain available until expended. Such sums as may be necessary may be transferred from the Food and Drug Administration salaries and expenses appropriation account without fiscal year limitation to such appropriation account for salaries and expenses with such fiscal year limitation.

''(2) AVAILABILITY.—

''(A) IN GENERAL.—Fees appropriated under paragraph (3) are available only for the purpose of paying the costs of the activities of the Food and Drug Administration related to the regulation of tobacco products under this chapter and the Family Smoking Prevention and Tobacco Control Act (referred to in this subsection as 'tobacco regulation activities'), except that such fees may be used for the reimbursement specified in subparagraph (C).

''(B) PROHIBITION AGAINST USE OF OTHER FUNDS.—

''(i) IN GENERAL.—Except as provided in clause (ii), fees collected under subsection (a) are the only funds authorized to be made available for tobacco regulation activities.

''(ii) STARTUP COSTS.—Clause (i) does not apply until October 1, 2009. Until such date, any amounts available to the Food and Drug Administration (excluding user fees) shall be available and allocated as needed to pay the costs of tobacco regulation activities.

''(C) REIMBURSEMENT OF START-UP AMOUNTS.—

''(i) IN GENERAL.—Any amounts allocated for the start-up period pursuant to subparagraph (B)(ii) shall be reimbursed through any appropriated fees collected under subsection (a), in such manner as the Secretary determines appropriate to ensure that such allocation results in no net change in the total amount of funds otherwise available, for the period from October 1, 2008, through September 30, 2010, for Food and Drug Administration programs and activities (other than tobacco regulation activities) for such period.

''(ii) TREATMENT OF REIMBURSED AMOUNTS.—Amounts reimbursed under clause (i) shall be available for the programs and activities for which funds allocated for the start-up period were available, prior to such allocation, until September 30, 2010, notwithstanding any otherwise applicable limits on amounts for such programs or activities for a fiscal year.

''(D) FEE COLLECTED DURING START-UP PERIOD.—Notwithstanding the first sentence of paragraph (1), fees under subsection (a) may be collected through September 30, 2009 under subparagraph (B)(ii) and shall be available for obligation and remain available until expended. Such offsetting collections shall be credited to the salaries and expenses account of the Food and Drug Administration.

''(E) OBLIGATION OF START-UP COSTS IN ANTICIPATION OF AVAILABLE FEE COLLECTIONS.—Notwithstanding any other provision of law, following the enactment of an appropriation for fees under this section for fiscal year 2010, or any portion thereof, obligations for costs of tobacco regulation activities during the start-up period may be incurred in anticipation of the receipt of offsetting fee collections through procedures specified in section 1534 of title 31, United States Code.

''(3) AUTHORIZATION OF APPROPRIATIONS.—For fiscal year 2009 and each subsequent fiscal year, there is authorized to be appropriated for fees under this section an amount equal to the amount specified in subsection (b)(1) for the fiscal year.

''(d) COLLECTION OF UNPAID FEES.—In any case where the Secretary does not receive payment of a fee assessed under subsection (a) within 30 days after it is due, such fee shall be treated as a claim of the United States Government subject to subchapter II of chapter 37 of title 31, United States Code.

''(e) APPLICABILITY TO FISCAL YEAR 2009.—If the date of enactment of the Family Smoking Prevention and Tobacco Control Act occurs during fiscal year 2009, the following applies, subject to subsection (c):

''(1) The Secretary shall determine the fees that would apply for a single quarter of such fiscal year according to the application of subsection (b) to the amount specified in paragraph (1)(A) of such subsection (referred to in this subsection as the 'quarterly fee amounts').

''(2) For the quarter in which such date of enactment occurs, the amount of fees assessed shall be a pro rata amount, determined according to the number of days remaining in the quarter (including such date of enactment) and according to the daily equivalent of the quarterly fee amounts. Fees assessed under the preceding sentence shall not be collected until the next quarter.

''(3) For the quarter following the quarter to which paragraph (2) applies, the full quarterly fee amounts shall be assessed and collected, in addition to collection of the pro rata fees assessed under paragraph (2).''.

(c) CONFORMING AMENDMENT.—Section 9(1) of the Comprehensive Smokeless Tobacco Health Education Act of 1986 (15 U.S.C. 4408(i)) is amended to read as follows:

''(1) The term 'smokeless tobacco' has the meaning given such term by section 900(18) of the Federal Food, Drug, and Cosmetic Act.''.

SEC. 102. FINAL RULE.

(a) CIGARETTES AND SMOKELESS TOBACCO.—

(1) IN GENERAL.—On the first day of publication of the Federal Register that is 180 days or more after the date of enactment of this Act, the Secretary of Health and Human Services shall publish in the Federal Register a final rule regarding cigarettes and smokeless tobacco, which—

(A) is deemed to be issued under chapter 9 of the Federal Food, Drug, and Cosmetic Act, as added by section 101 of this division; and

(B) shall be deemed to be in compliance with all applicable provisions of chapter 5 of title 5, United States Code, and all other provisions of law relating to rulemaking procedures.

(2) CONTENTS OF RULE.—Except as provided in this subsection, the final rule published under paragraph (1), shall be identical in its provisions to part 897 of the regulations promulgated by the Secretary of Health and Human Services in the August 28, 1996, issue of the Federal Register (61 Fed. Reg. 44615–44618). Such rule shall—

(A) provide for the designation of jurisdictional authority that is in accordance with this subsection in accordance with this division and the amendments made by this division;

(B) strike Subpart C—Labels and section 897.32(c);

(C) strike paragraphs (a), (b), and (i) of section 897.3 and insert definitions of the terms ''cigarette'', ''cigarette tobacco'', and ''smokeless tobacco'' as defined in section 900 of the Federal Food, Drug, and Cosmetic Act;

(D) insert ''or roll-your-own paper'' in section 897.34(a) after ''other than cigarettes or smokeless tobacco'';

(E) include such modifications to section 897.30(b), if any, that the Secretary determines are appropriate in light of governing First Amendment case law, including the decision of the Supreme Court of the United States in Lorillard Tobacco Co. v. Reilly (533 U.S. 525 (2001));

(F) become effective on the date that is 1 year after the date of enactment of this Act; and

(G) amend paragraph (d) of section 897.16 to read as follows:

''(d)(1) Except as provided in subparagraph (2), no manufacturer, distributor, or retailer may distribute or cause to be distributed any free samples of cigarettes, smokeless tobacco, or other tobacco products (as such term is defined in section 201 of the Federal Food, Drug, and Cosmetic Act).

''(2)(A) Subparagraph (1) does not prohibit a manufacturer, distributor, or retailer from distributing or causing to be distributed free samples of smokeless tobacco in a qualified adult-only facility.

''(B) This subparagraph does not affect the authority of a State or local government to prohibit or otherwise restrict the distribution of free samples of smokeless tobacco.

''(C) For purposes of this paragraph, the term 'qualified adult-only facility' means a facility or restricted area that—

''(i) requires each person present to provide to a law enforcement officer (whether on or off duty) or to a security guard licensed by a governmental entity government-issued identification showing a photograph and at least the minimum age established by applicable law for the purchase of smokeless tobacco;

''(ii) does not sell, serve, or distribute alcohol;

''(iii) is not located adjacent to or immediately across from (in any direction) a space that is used primarily for youth-oriented marketing, promotional, or other activities;

''(iv) is a temporary structure constructed, designated, and operated as a distinct enclosed area for the purpose of distributing free samples of smokeless tobacco in accordance with this subparagraph;

''(v) is enclosed by a barrier that—

''(I) is constructed of, or covered with, an opaque material (except for entrances and exits);

''(II) extends from no more than 12 inches above the ground or floor (which area at the bottom of the barrier must be covered with material that restricts visibility but may allow airflow) to at least 8 feet above the ground or floor (or to the ceiling); and

''(III) prevents persons outside the qualified adult-only facility from seeing into the qualified adult-only facility, unless they make unreasonable efforts to do so; and

''(vi) does not display on its exterior—

''(I) any tobacco product advertising;

''(II) a brand name other than in conjunction with words for an area or enclosure to identify an adult-only facility; or

''(III) any combination of words that would imply to a reasonable observer that the manufacturer, distributor, or retailer has a sponsorship that would violate section 897.34(c).

''(D) Distribution of samples of smokeless tobacco under this subparagraph permitted to be taken out of the qualified adult-only facility shall be limited to 1 package per adult consumer containing no more than 0.53 ounces (15 grams) of smokeless tobacco. If such package of smokeless tobacco contains individual portions of smokeless tobacco, the

individual portions of smokeless tobacco shall not exceed 8 individual portions and the collective weight of such individual portions shall not exceed 0.53 ounces (15 grams). Any manufacturer, distributor, or retailer who distributes or causes to be distributed free samples also shall take reasonable steps to ensure that the above amounts are limited to one such package per adult consumer per day.

''(3) Notwithstanding subparagraph (2), no manufacturer, distributor, or retailer may distribute or cause to be distributed any free samples of smokeless tobacco—

''(A) to a sports team or entertainment group; or

''(B) at any football, basketball, baseball, soccer, or hockey event or any other sporting or entertainment event determined by the Secretary to be covered by this subparagraph.

''(4) The Secretary shall implement a program to ensure compliance with this paragraph and submit a report to the Congress on such compliance not later than 18 months after the date of enactment of the Family Smoking Prevention and Tobacco Control Act.

''(5) Nothing in this paragraph shall be construed to authorize any person to distribute or cause to be distributed any sample of a tobacco product to any individual who has not attained the minimum age established by applicable law for the purchase of such product.''.

(3) AMENDMENTS TO RULE.—Prior to making amendments to the rule published under paragraph (1), the Secretary shall promulgate a proposed rule in accordance with chapter 5 of title 5, United States Code.

(4) RULE OF CONSTRUCTION.—Except as provided in paragraph (3), nothing in this section shall be construed to limit the authority of the Secretary to amend, in accordance with chapter 5 of title 5, United States Code, the regulation promulgated pursuant to this section, including the provisions of such regulation relating to distribution of free samples.

(5) ENFORCEMENT OF RETAIL SALE PROVISIONS.—The Secretary of Health and Human Services shall ensure that the provisions of this division, the amendments made by this division, and the implementing regulations (including such provisions, amendments, and regulations relating to the retail sale of tobacco products) are enforced with respect to the United States and Indian tribes.

(6) QUALIFIED ADULT-ONLY FACILITY.—A qualified adult-only facility (as such term is defined in section 897.16(d) of the final rule published under paragraph (1)) that is also a retailer and that commits a violation as a retailer shall not be subject to the limitations in section 103(q) and shall be subject to penalties applicable to a qualified adult-only facility.

(7) CONGRESSIONAL REVIEW PROVISIONS.—Section 801 of title 5, United States Code, shall not apply to the final rule published under paragraph (1).

(b) LIMITATION ON ADVISORY OPINIONS.—As of the date of enactment of this Act, the following documents issued by the Food and Drug Administration shall not constitute advisory opinions under section 10.85(d)(1) of title 21, Code of Federal Regulations, except as they apply to tobacco products, and shall not be cited by the Secretary of Health and Human Services or the Food and Drug Administration as binding precedent:

(1) The preamble to the proposed rule in the document titled ''Regulations Restricting the Sale and Distribution of Cigarettes and Smokeless Tobacco Products to Protect Children and Adolescents'' (60 Fed. Reg. 41314–41372 (August 11, 1995)).

(2) The document titled ''Nicotine in Cigarettes and Smokeless Tobacco Products is a Drug and These Products Are Nicotine Delivery Devices Under the Federal Food, Drug, and Cosmetic Act'' (60 Fed. Reg. 41453–41787 (August 11, 1995)).

(3) The preamble to the final rule in the document titled ''Regulations Restricting the Sale and Distribution of Cigarettes and Smokeless Tobacco to Protect Children and Adolescents'' (61 Fed. Reg. 44396–44615 (August 28, 1996)).

(4) The document titled ''Nicotine in Cigarettes and Smokeless Tobacco is a Drug and These Products are Nicotine Delivery Devices Under the Federal Food, Drug, and Cosmetic Act; Jurisdictional Determination'' (61 Fed. Reg. 44619–45318 (August 28, 1996)).

SEC. 103. CONFORMING AND OTHER AMENDMENTS TO GENERAL PROVISIONS.

(a) AMENDMENT OF FEDERAL FOOD, DRUG, AND COSMETIC ACT.—Except as otherwise expressly provided, whenever in this section an amendment is expressed in terms of an amendment to, or repeal of, a section or other provision, the reference is to a section or other provision of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.).

(b) SECTION 301.—Section 301 (21 U.S.C. 331) is amended—

(1) in subsection (a), by inserting ''tobacco product,'' after ''device,'';

(2) in subsection (b), by inserting ''tobacco product,'' after ''device,'';

(3) in subsection (c), by inserting ''tobacco product,'' after ''device,'';

(4) in subsection (e)—

(A) by striking the period after ''572(i)''; and

(B) by striking ''or 761 or the refusal to permit access to'' and inserting ''761, 909, or 920 or the refusal to permit access to'';

(5) in subsection (g), by inserting ''tobacco product,'' after ''device,'';

(6) in subsection (h), by inserting ''tobacco product,'' after ''device,'';

(7) in subsection (j)—

(A) by striking the period after ''573''; and

(B) by striking ''708, or 721'' and inserting ''708, 721, 904, 905, 906, 907, 908, 909, or 920(b)'';

(8) in subsection (k), by inserting ''tobacco product,'' after ''device,'';

(9) by striking subsection (p) and inserting the following:

''(p) The failure to register in accordance with section 510 or 905, the failure to provide any information required by section 510(j), 510(k), 905(i), or 905(j), or the failure to provide a notice required by section 510(j)(2) or 905(i)(3).'';

(10) by striking subsection (q)(1) and inserting the following:

''(q)(1) The failure or refusal—

''(A) to comply with any requirement prescribed under section 518, 520(g), 903(b), 907, 908, or 915;

''(B) to furnish any notification or other material or information required by or under section 519, 520(g), 904, 909, or 920; or

''(C) to comply with a requirement under section 522 or 913.'';

(11) in subsection (q)(2), by striking ''device,'' and inserting ''device or tobacco product,'';

(12) in subsection (r), by inserting ''or tobacco product'' after the term ''device'' each time that such term appears; and

(13) by adding at the end the following:

''(oo) The sale of tobacco products in violation of a no-tobacco-sale order issued under section 303(f).

''(pp) The introduction or delivery for introduction into interstate commerce of a tobacco product in violation of section 911.

''(qq)(1) Forging, counterfeiting, simulating, or falsely representing, or without proper authority using any mark, stamp (including tax stamp), tag, label, or other identification device upon any tobacco product or container or labeling thereof so as to render such tobacco product a counterfeit tobacco product.

''(2) Making, selling, disposing of, or keeping in possession, control, or custody, or concealing any punch, die, plate, stone, or other item that is designed to print, imprint, or reproduce the trademark, trade name, or other identifying mark, imprint, or device of another or any likeness of any of the foregoing upon any tobacco product or container or labeling thereof so as to render such tobacco product a counterfeit tobacco product.

''(3) The doing of any act that causes a tobacco product to be a counterfeit tobacco product, or the sale or dispensing, or the holding for sale or dispensing, of a counterfeit tobacco product.

''(rr) The charitable distribution of tobacco products.

''(ss) The failure of a manufacturer or distributor to notify the Attorney General and the Secretary of the Treasury of their knowledge of tobacco products used in illicit trade.

''(tt) Making any express or implied statement or representation directed to consumers with respect to a tobacco product, in a label or labeling or through the media or advertising, that either conveys, or misleads or would mislead consumers into believing, that—

''(1) the product is approved by the Food and Drug Administration;

''(2) the Food and Drug Administration deems the product to be safe for use by consumers;

''(3) the product is endorsed by the Food and Drug Administration for use by consumers; or

''(4) the product is safe or less harmful by virtue of—

''(A) its regulation or inspection by the Food and Drug Administration; or

''(B) its compliance with regulatory requirements set by the Food and Drug Administration;

including any such statement or representation rendering the product misbranded under section 903.''.

(c) SECTION 303.—Section 303(f) (21 U.S.C. 333(f)) is amended—

(1) in paragraph (5)—

(A) by striking ''paragraph (1), (2), (3), or (4)'' each place such appears and inserting ''paragraph (1), (2), (3), (4), or (9)'';

(B) in subparagraph (A)—

(i) by striking ''assessed'' the first time it appears and inserting ''assessed, or a no-tobacco-sale order may be imposed,''; and

(ii) by striking ''penalty'' the second time it appears and inserting ''penalty, or upon whom a no-tobacco-sale order is to be imposed,'';

(C) in subparagraph (B)—

(i) by inserting after ''penalty,'' the following: ''or the period to be covered by a no-tobacco-sale order,''; and

(ii) by adding at the end the following: ''A no-tobacco-sale order permanently prohibiting an individual retail outlet from selling tobacco products shall include provisions that allow the outlet, after a specified period of time, to request that the Secretary compromise, modify, or terminate the order.''; and

(D) by adding at the end the following:

''(D) The Secretary may compromise, modify, or terminate, with or without conditions, any no-tobacco-sale order.'';

(2) in paragraph (6)—

(A) by inserting ''or the imposition of a no-tobacco-sale order'' after the term ''penalty'' each place such term appears; and

(B) by striking ''issued.'' and inserting ''issued, or on which the no-tobacco-sale order was imposed, as the case may be.''; and

(3) by adding at the end the following:

''(8) If the Secretary finds that a person has committed repeated violations of restrictions promulgated under section 906(d) at a particular retail outlet then the Secretary may impose a no-tobacco-sale order on that person prohibiting the sale of tobacco products in that outlet. A no-tobacco-sale order may be imposed with a civil penalty under paragraph (1). Prior to the entry of a no-sale order under this paragraph, a person shall be entitled to a hearing pursuant to the procedures established through regulations of the Food and Drug Administration for assessing civil money penalties, including at a retailer's request a hearing by telephone, or at the nearest regional or field office of the Food and Drug Administration, or at a Federal, State, or county facility within 100 miles from the location of the retail outlet, if such a facility is available.

''(9) CIVIL MONETARY PENALTIES FOR VIOLATION OF TOBACCO PRODUCT REQUIREMENTS.—

''(A) IN GENERAL.—Subject to subparagraph (B), any person who violates a requirement of this Act which relates to tobacco products shall be liable to the United States for a civil penalty in an amount not to exceed $15,000 for each such violation, and not to exceed $1,000,000 for all such violations adjudicated in a single proceeding.

''(B) ENHANCED PENALTIES.—

''(i) Any person who intentionally violates a requirement of section 902(5), 902(6), 904, 908(c), or 911(a), shall be subject to a civil monetary penalty of—

''(I) not to exceed $250,000 per violation, and not to exceed $1,000,000 for all such violations adjudicated in a single proceeding; or

''(II) in the case of a violation that continues after the Secretary provides written notice to such person, $250,000 for the first 30-day period (or any portion thereof) that the person continues to be in violation, and such amount shall double for every 30-day period thereafter that the violation continues, not to exceed $1,000,000 for any 30-day period, and not to exceed $10,000,000 for all such violations adjudicated in a single proceeding.

''(ii) Any person who violates a requirement of section 911(g)(2)(C)(ii) or 911(i)(1), shall be subject to a civil monetary penalty of—

''(I) not to exceed $250,000 per violation, and not to exceed $1,000,000 for all such violations adjudicated in a single proceeding; or

''(II) in the case of a violation that continues after the Secretary provides written notice to such person, $250,000 for the first 30-day period (or any portion thereof) that the person continues to be in violation, and such amount shall double for every 30-day period thereafter that the violation continues, not to exceed $1,000,000 for any 30-day period, and not to exceed $10,000,000 for all such violations adjudicated in a single proceeding.

''(iii) In determining the amount of a civil penalty under clause (i)(II) or (ii)(II), the Secretary shall take into consideration whether the person is making efforts toward correcting the violation of the requirements of the section for which such person is subject to such civil penalty.''.

(d) SECTION 304.—Section 304 (21 U.S.C. 334) is amended—

(1) in subsection (a)(2)—

(A) by striking ''and'' before ''(D)''; and

(B) by striking ''device.'' and inserting the following: ''device, and (E) Any adulterated or misbranded tobacco product.'';

(2) in subsection (d)(1), by inserting ''tobacco product,'' after ''device,'';

(3) in subsection (g)(1), by inserting ''or tobacco product'' after the term ''device'' each place such term appears; and

(4) in subsection (g)(2)(A), by inserting ''or tobacco product'' after ''device''.

(e) SECTION 505.—Section 505(n)(2) (21 U.S.C. 355(n)(2)) is amended by striking ''section 904'' and inserting ''section 1004''.

(f) SECTION 523.—Section 523(b)(2)(D) (21 U.S.C. 360m(b)(2)(D)) is amended by striking ''section 903(g)'' and inserting ''section 1003(g)''.

(g) SECTION 702.—Section 702(a)(1) (U.S.C. 372(a)(1)) is amended—

(1) by striking ''(a)(1)'' and inserting ''(a)(1)(A)''; and

(2) by adding at the end the following:

''(B)(i) For a tobacco product, to the extent feasible, the Secretary shall contract with the States in accordance with this paragraph to carry out inspections of retailers within that State in connection with the enforcement of this Act.

''(ii) The Secretary shall not enter into any contract under clause (i) with the government of any of the several States to exercise enforcement authority under this Act on Indian country without the express written consent of the Indian tribe involved.''.

(h) SECTION 703.—Section 703 (21 U.S.C. 373) is amended—

(1) by inserting ''tobacco product,'' after the term ''device,'' each place such term appears; and

(2) by inserting ''tobacco products,'' after the term ''devices,'' each place such term appears.

(i) SECTION 704.—Section 704 (21 U.S.C. 374) is amended—

(1) in subsection (a)(1)—

(A) by striking ''devices, or cosmetics'' each place it appears and inserting ''devices, tobacco products, or cosmetics'';

(B) by striking ''or restricted devices'' each place it appears and inserting ''restricted devices, or tobacco products''; and

(C) by striking ''and devices and subject to'' and all that follows through ''other drugs or devices'' and inserting ''devices, and tobacco products and subject to reporting and inspection under regulations lawfully issued pursuant to section 505 (i) or (k), section 519, section 520(g), or chapter IX and data relating to other drugs, devices, or tobacco products'';

(2) in subsection (b), by inserting ''tobacco product,'' after ''device,''; and

(3) in subsection (g)(13), by striking ''section 903(g)'' and inserting ''section 1003(g)''.

(j) SECTION 705.—Section 705(b) (21 U.S.C. 375(b)) is amended by inserting ''tobacco products,'' after ''devices,''.

(k) SECTION 709.—Section 709 (21 U.S.C. 379a) is amended by inserting ''tobacco product,'' after ''device,''.

(l) SECTION 801.—Section 801 (21 U.S.C. 381) is amended—

(1) in subsection (a)—

(A) by inserting ''tobacco products,'' after the term ''devices,'';

(B) by inserting ''or section 905(h)'' after ''section 510''; and

(C) by striking the term ''drugs or devices'' each time such term appears and inserting ''drugs, devices, or tobacco products'';

(2) in subsection (e)(1)—

(A) by inserting ''tobacco product'' after ''drug, device,''; and

(B) by inserting '', and a tobacco product intended for export shall not be deemed to be in violation of section 906(e), 907, 911, or 920(a),'' before ''if it—''; and

(3) by adding at the end the following:

''(p)(1) Not later than 36 months after the date of enactment of the Family Smoking Prevention and Tobacco Control Act, and annually thereafter, the Secretary shall submit to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives, a report regarding—

''(A) the nature, extent, and destination of United States tobacco product exports that do not conform to tobacco product standards established pursuant to this Act;

''(B) the public health implications of such exports, including any evidence of a negative public health impact; and

''(C) recommendations or assessments of policy alternatives available to Congress and the executive branch to reduce any negative public health impact caused by such exports.

''(2) The Secretary is authorized to establish appropriate information disclosure requirements to carry out this subsection.''.

(m) SECTION 1003.—Section 1003(d)(2)(C) (as redesignated by section 101(b)) is amended—

(1) by striking ''and'' after ''cosmetics,''; and

(2) inserting '', and tobacco products'' after ''devices''.

(n) SECTION 1009.—Section 1009(b) (as redesignated by section 101(b)) is amended by striking ''section 908'' and inserting ''section 1008''.

(o) SECTION 409 OF THE FEDERAL MEAT INSPECTION ACT.—Section 409(a) of the Federal Meat Inspection Act (21 U.S.C. 679(a)) is amended by striking ''section 902(b)'' and inserting ''section 1002(b)''.

(p) RULE OF CONSTRUCTION.—Nothing in this section is intended or shall be construed to expand, contract, or otherwise modify or amend the existing limitations on State government authority over tribal restricted fee or trust lands.

(q) GUIDANCE AND EFFECTIVE DATES.—

(1) IN GENERAL.—The Secretary of Health and Human Services shall issue guidance—

(A) defining the term ''repeated violation'', as used in section 303(f)(8) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 333(f)(8)) as amended by subsection (c), as including at least 5 violations of particular requirements over a 36-month period at a particular retail outlet that constitute a repeated violation and providing for civil penalties in accordance with paragraph (2);

(B) providing for timely and effective notice by certified or registered mail or personal delivery to the retailer of each alleged violation at a particular retail outlet prior to conducting a followup compliance check, such notice to be sent to the location specified on the retailer's registration or to the retailer's registered agent if the retailer has provider such agent information to the Food and Drug Administration prior to the violation;

(C) providing for a hearing pursuant to the procedures established through regulations of the Food and Drug Administration for assessing civil money penalties, including at a retailer's request a hearing by telephone or at the nearest regional or field office of the Food and Drug Administration, and providing for an expedited procedure for the administrative appeal of an alleged violation;

(D) providing that a person may not be charged with a violation at a particular retail outlet unless the Secretary has provided notice to the retailer of all previous violations at that outlet;

(E) establishing that civil money penalties for multiple violations shall increase from one violation to the next violation pursuant to paragraph (2) within the time periods provided for in such paragraph;

(F) providing that good faith reliance on the presentation of a false government-issued photographic identification that contains a date of birth does not constitute a violation of any minimum age requirement for the sale of tobacco products if the retailer has taken effective steps to prevent such violations, including—

(i) adopting and enforcing a written policy against sales to minors;

(ii) informing its employees of all applicable laws;

(iii) establishing disciplinary sanctions for employee noncompliance; and

(iv) requiring its employees to verify age by way of photographic identification or electronic scanning device; and

(G) providing for the Secretary, in determining whether to impose a no-tobacco-sale order and in determining whether to compromise, modify, or terminate such an order, to consider whether the retailer has taken effective steps to prevent violations of the minimum age requirements for the sale of tobacco products, including the steps listed in subparagraph (F).

(2) PENALTIES FOR VIOLATIONS.—

(A) IN GENERAL.—The amount of the civil penalty to be applied for violations of restrictions promulgated under section 906(d), as described in paragraph (1), shall be as follows:

(i) With respect to a retailer with an approved training program, the amount of the civil penalty shall not exceed—

(I) in the case of the first violation, $0.00 together with the issuance of a warning letter to the retailer;

(II) in the case of a second violation within a 12-month period, $250;

(III) in the case of a third violation within a 24-month period, $500;

(IV) in the case of a fourth violation within a 24-month period, $2,000;

(V) in the case of a fifth violation within a 36-month period, $5,000; and

(VI) in the case of a sixth or subsequent violation within a 48-month period, $10,000 as determined by the Secretary on a case-by-case basis.

(ii) With respect to a retailer that does not have an approved training program, the amount of the civil penalty shall not exceed—

(I) in the case of the first violation, $250;

(II) in the case of a second violation within a 12-month period, $500;

(III) in the case of a third violation within a 24-month period, $1,000;

(IV) in the case of a fourth violation within a 24-month period, $2,000;

(V) in the case of a fifth violation within a 36-month period, $5,000; and

(VI) in the case of a sixth or subsequent violation within a 48-month period, $10,000 as determined by the Secretary on a case-by-case basis.

(B) TRAINING PROGRAM.—For purposes of subparagraph (A), the term ''approved training program'' means a training program that complies with standards developed by the Food and Drug Administration for such programs.

(C) CONSIDERATION OF STATE PENALTIES.—The Secretary shall coordinate with the States in enforcing the provisions of this Act and, for purposes of mitigating a civil penalty to be applied for a violation by a retailer of any restriction promulgated under section 906(d), shall consider the amount of any penalties paid by the retailer to a State for the same violation.

(3) GENERAL EFFECTIVE DATE.—The amendments made by paragraphs (2), (3), and (4) of subsection (c) shall take effect upon the issuance of guidance described in paragraph (1) of this subsection.

(4) SPECIAL EFFECTIVE DATE.—The amendment made by subsection (c)(1) shall take effect on the date of enactment of this Act.

(5) PACKAGE LABEL REQUIREMENTS.—The package label requirements of paragraphs (3) and (4) of section 903(a) of the Federal Food, Drug, and Cosmetic Act (as amended by this division) shall take effect on the date that is 12 months after the date of enactment of this Act. The package label requirements of paragraph (2) of such section 903(a) for cigarettes shall take effect on the date that is 15 months after the issuance of the regulations required by section 4(d) of the Federal Cigarette Labeling and Advertising Act (15 U.S.C. 1333), as amended by section 201 of this division. The package label requirements of paragraph (2) of such section 903(a) for tobacco products other than cigarettes shall take effect on the date that is 12 months after the date of enactment of this Act. The effective date shall be with respect to the date of manufacture, provided that, in any case, beginning 30 days after such effective date, a manufacturer shall not introduce into the domestic commerce of the United States any product, irrespective of the date of manufacture, that is not in conformance with section 903(a) (2), (3), and (4) and section 920(a) of the Federal Food, Drug, and Cosmetic Act.

(6) ADVERTISING REQUIREMENTS.—The advertising requirements of section 903(a)(8) of the Federal Food, Drug, and Cosmetic Act (as amended by this division) shall take effect on the date that is 12 months after the date of enactment of this Act.

SEC. 104. STUDY ON RAISING THE MINIMUM AGE TO PURCHASE TOBACCO PRODUCTS.

The Secretary of Health and Human Services shall—

(1) convene an expert panel to conduct a study on the public health implications of raising the minimum age to purchase tobacco products; and

(2) not later than 5 years after the date of enactment of this Act, submit a report to the Congress on the results of such study.

SEC. 105. ENFORCEMENT ACTION PLAN FOR ADVERTISING AND PROMOTION RESTRICTIONS.

(a) ACTION PLAN.—

(1) DEVELOPMENT.—Not later than 6 months after the date of enactment of this Act, the Secretary of Health and Human Services (in this section referred to as the ''Secretary'') shall develop and publish an action plan to enforce restrictions adopted pursuant to section 906 of the Federal Food, Drug, and Cosmetic Act, as added by section 101(b) of this division, or pursuant to section 102(a) of this division, on promotion and advertising of menthol and other cigarettes to youth.

(2) CONSULTATION.—The action plan required by paragraph (1) shall be developed in consultation with public health organizations and other stakeholders with demonstrated expertise and experience in serving minority communities.

(3) PRIORITY.—The action plan required by paragraph (1) shall include provisions designed to ensure enforcement of the restrictions described in paragraph (1) in minority communities.

(b) STATE AND LOCAL ACTIVITIES.—

(1) INFORMATION ON AUTHORITY.—Not later than 3 months after the date of enactment of this Act, the Secretary shall inform State, local, and tribal governments of the authority provided to such entities under section 5(c) of the Federal Cigarette Labeling and Advertising Act, as added by section 203 of this division, or preserved by such entities under section 916 of the Federal Food, Drug, and Cosmetic Act, as added by section 101(b) of this division.

(2) COMMUNITY ASSISTANCE.—At the request of communities seeking assistance to prevent underage tobacco use, the Secretary shall provide such assistance, including assistance with strategies to address the prevention of underage tobacco use in communities with a disproportionate use of menthol cigarettes by minors.

SEC. 106. STUDIES OF PROGRESS AND EFFECTIVENESS.

(a) FDA REPORT.—Not later than 3 years after the date of enactment of this Act, and not less than every 2 years thereafter, the Secretary of Health and Human Services shall submit to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives, a report concerning—

(1) the progress of the Food and Drug Administration in implementing this division, including major accomplishments, objective measurements of progress, and the identification of any areas that have not been fully implemented;

(2) impediments identified by the Food and Drug Administration to progress in implementing this division and to meeting statutory timeframes;

(3) data on the number of new product applications received under section 910 of the Federal Food, Drug, and Cosmetic Act and modified risk product applications received under section 911 of such Act, and the number of applications acted on under each category; and

(4) data on the number of full time equivalents engaged in implementing this division.

(b) GAO REPORT.—Not later than 5 years after the date of enactment of this Act, the Comptroller General of the United States shall conduct a study of, and submit to the Committees described in subsection (a) a report concerning—

(1) the adequacy of the authority and resources provided to the Secretary of Health and Human Services for this division to carry out its goals and purposes; and

(2) any recommendations for strengthening that authority to more effectively protect the public health with respect to the manufacture, marketing, and distribution of tobacco products.

(c) PUBLIC AVAILABILITY.—The Secretary of Health and Human Services and the Comptroller General of the United States, respectively, shall make the reports required under subsection (a) and (b) available to the public, including by posting such reports on the respective Internet websites of the Food and Drug Administration and the Government Accountability Office.

TITLE II—TOBACCO PRODUCT WARNINGS; CONSTITUENT AND SMOKE CONSTITUENT DISCLOSURE

SEC. 201. CIGARETTE LABEL AND ADVERTISING WARNINGS.

(a) AMENDMENT.—Section 4 of the Federal Cigarette Labeling and Advertising Act (15 U.S.C. 1333) is amended to read as follows:

''SEC. 4. LABELING.

''(a) LABEL REQUIREMENTS.—

''(1) IN GENERAL.—It shall be unlawful for any person to manufacture, package, sell, offer to sell, distribute, or import for sale or distribution within the United States any cigarettes the package of which fails to bear, in accordance with the requirements of this section, one of the following labels:

''WARNING: Cigarettes are addictive.

''WARNING: Tobacco smoke can harm your children.

''WARNING: Cigarettes cause fatal lung disease.

''WARNING: Cigarettes cause cancer.

''WARNING: Cigarettes cause strokes and heart disease.

''WARNING: Smoking during pregnancy can harm your baby.

''WARNING: Smoking can kill you.

''WARNING: Tobacco smoke causes fatal lung disease in nonsmokers.

''WARNING: Quitting smoking now greatly reduces serious risks to your health.

''(2) PLACEMENT; TYPOGRAPHY; ETC.—Each label statement required by paragraph (1) shall be located in the upper portion of the front and rear panels of the package, directly on the package underneath the cellophane or other clear wrapping. Each label statement shall comprise the top 50 percent of the front and rear panels of the package. The word

'WARNING' shall appear in capital letters and all text shall be in conspicuous and legible 17-point type, unless the text of the label statement would occupy more than 70 percent of such area, in which case the text may be in a smaller conspicuous and legible type size, provided that at least 60 percent of such area is occupied by required text. The text shall be black on a white background, or white on a black background, in a manner that contrasts, by typography, layout, or color, with all other printed material on the package, in an alternating fashion under the plan submitted under subsection (c).

''(3) DOES NOT APPLY TO FOREIGN DISTRIBUTION.—The provisions of this subsection do not apply to a tobacco product manufacturer or distributor of cigarettes which does not manufacture, package, or import cigarettes for sale or distribution within the United States.

''(4) APPLICABILITY TO RETAILERS.—A retailer of cigarettes shall not be in violation of this subsection for packaging that—

''(A) contains a warning label;

''(B) is supplied to the retailer by a license- or permit-holding tobacco product manufacturer, importer, or distributor; and

''(C) is not altered by the retailer in a way that is material to the requirements of this subsection.

''(b) ADVERTISING REQUIREMENTS.—

''(1) IN GENERAL.—It shall be unlawful for any tobacco product manufacturer, importer, distributor, or retailer of cigarettes to advertise or cause to be advertised within the United States any cigarette unless its advertising bears, in accordance with the requirements of this section, one of the labels specified in subsection (a).

''(2) TYPOGRAPHY, ETC.—Each label statement required by subsection (a) in cigarette advertising shall comply with the standards set forth in this paragraph. For press and poster advertisements, each such statement and (where applicable) any required statement relating to tar, nicotine, or other constituent (including a smoke constituent) yield shall comprise at least 20 percent of the area of the advertisement and shall appear in a conspicuous and prominent format and location at the top of each advertisement within the trim area. The Secretary may revise the required type sizes in such area in such manner as the Secretary determines appropriate. The word 'WARNING' shall appear in capital letters, and each label statement shall appear in conspicuous and legible type. The text of the label statement shall be black if the background is white and white if the background is black, under the plan submitted under subsection (c). The label statements shall be enclosed by a rectangular border that is the same color as the letters of the statements and that is the width of the first downstroke of the capital 'W' of the word 'WARNING' in the label statements. The text of such label statements shall be in a typeface pro rata to the following requirements: 45-point type for a whole-page broadsheet newspaper advertisement; 39-point type for a half-page broadsheet newspaper advertisement; 39-point type for a whole-page tabloid newspaper advertisement; 27-point type for a half-page tabloid newspaper advertisement; 31.5-point type for a double page spread magazine or whole-page magazine advertisement; 22.5-point type for a 28 centimeter by 3 column advertisement; and 15-point type for a 20 centimeter by 2 column advertisement. The label statements shall be in English, except that—

''(A) in the case of an advertisement that appears in a newspaper, magazine, periodical, or other publication that is not in English, the statements shall appear in the predominant language of the publication; and

''(B) in the case of any other advertisement that is not in English, the statements shall appear in the same language as that principally used in the advertisement.

''(3) MATCHBOOKS.—Notwithstanding paragraph (2), for matchbooks (defined as containing not more than 20 matches) customarily given away with the purchase of tobacco products, each label statement required by subsection (a) may be printed on the inside cover of the matchbook.

''(4) ADJUSTMENT BY SECRETARY.—The Secretary may, through a rulemaking under section 553 of title 5, United States Code, adjust the format and type sizes for the label statements required by this section; the text, format, and type sizes of any required tar, nicotine yield, or other constituent (including smoke constituent) disclosures; or the text, format, and type sizes for any other disclosures required under the Federal Food, Drug, and Cosmetic Act. The text of any such label statements or disclosures shall be required to appear only within the 20 percent area of cigarette advertisements provided by paragraph (2). The Secretary shall promulgate regulations which provide for adjustments in the format and type sizes of any text required to appear in such area to ensure that the total text required to appear by law will fit within such area.

''(c) MARKETING REQUIREMENTS.—

''(1) RANDOM DISPLAY.—The label statements specified in subsection (a)(1) shall be randomly displayed in each 12-month period, in as equal a number of times as is possible on each brand of the product and be randomly distributed in all areas of the United States in which the product is marketed in accordance with a plan submitted by the tobacco product manufacturer, importer, distributor, or retailer and approved by the Secretary.

''(2) ROTATION.—The label statements specified in subsection (a)(1) shall be rotated quarterly in alternating sequence in advertisements for each brand of cigarettes in accordance with a plan submitted by the tobacco product manufacturer, importer, distributor, or retailer to, and approved by, the Secretary.

''(3) REVIEW.—The Secretary shall review each plan submitted under paragraph (2) and approve it if the plan—

''(A) will provide for the equal distribution and display on packaging and the rotation required in advertising under this subsection; and

''(B) assures that all of the labels required under this section will be displayed by the tobacco product manufacturer, importer, distributor, or retailer at the same time.

''(4) APPLICABILITY TO RETAILERS.—This subsection and subsection (b) apply to a retailer only if that retailer is responsible for or directs the label statements required under this section except that this paragraph shall not relieve a retailer of liability if the retailer displays, in a location open to the public, an advertisement that does not contain a warning label or has been altered by the retailer in a way that is material to the requirements of this subsection and subsection (b).

''(d) GRAPHIC LABEL STATEMENTS.—Not later than 24 months after the date of enactment of the Family Smoking Prevention and Tobacco Control Act, the Secretary shall issue regulations that require color graphics depicting the negative health consequences of smoking to accompany the label statements specified in subsection (a)(1). The Secretary may adjust the type size, text and format of the label statements specified in subsections (a)(2) and (b)(2) as the Secretary determines appropriate so that both the graphics and the accompanying label statements are clear, conspicuous, legible and appear within the specified area.''.

(b) EFFECTIVE DATE.—The amendment made by subsection (a) shall take effect 15 months after the issuance of the regulations required by subsection (a). Such effective date shall be with respect to the date of manufacture, provided that, in any case, beginning 30 days after such effective date, a manufacturer shall not introduce into the domestic commerce of the United States any product, irrespective of the date of manufacture, that is not in conformance with section 4 of the Federal Cigarette Labeling and Advertising Act (15 U.S.C. 1333), as amended by subsection (a).

SEC. 202. AUTHORITY TO REVISE CIGARETTE WARNING LABEL STATEMENTS.

(a) PREEMPTION.—Section 5(a) of the Federal Cigarette Labeling and Advertising Act (15 U.S.C. 1334(a)) is amended by striking ''No'' and inserting ''Except to the extent the Secretary requires additional or different statements on any cigarette package by a regulation, by an order, by a standard, by an authorization to market a product, or by a condition of marketing a product, pursuant to the Family Smoking Prevention and Tobacco Control Act (and the amendments made by that Act), or as required under section 903(a)(2) or section 920(a) of the Federal Food, Drug, and Cosmetic Act, no''.

(b) CHANGE IN REQUIRED STATEMENTS.—Section 4 of the Federal Cigarette Labeling and Advertising Act (15 U.S.C. 1333), as amended by section 201, is further amended by adding at the end the following:

''(d) CHANGE IN REQUIRED STATEMENTS.—The Secretary through a rulemaking conducted under section 553 of title 5, United States Code, may adjust the format, type size, color graphics, and text of any of the label requirements, or establish the format, type size, and text of any other disclosures required under the Federal Food, Drug, and Cosmetic Act, if the Secretary finds that such a change would promote greater public understanding of the risks associated with the use of tobacco products.''.

SEC. 203. STATE REGULATION OF CIGARETTE ADVERTISING AND PROMOTION.

Section 5 of the Federal Cigarette Labeling and Advertising Act (15 U.S.C. 1334) is amended by adding at the end the following:

''(c) EXCEPTION.—Notwithstanding subsection (b), a State or locality may enact statutes and promulgate regulations, based on smoking and health, that take effect after the effective date of the Family Smoking Prevention and Tobacco Control Act, imposing specific bans or restrictions on the time, place, and manner, but not content, of the advertising or promotion of any cigarettes.''.

SEC. 204. SMOKELESS TOBACCO LABELS AND ADVERTISING WARNINGS.

(a) AMENDMENT.—Section 3 of the Comprehensive Smokeless Tobacco Health Education Act of 1986 (15 U.S.C. 4402) is amended to read as follows:

''SEC. 3. SMOKELESS TOBACCO WARNING.

''(a) GENERAL RULE.—

''(1) It shall be unlawful for any person to manufacture, package, sell, offer to sell, distribute, or import for sale or distribution within the United States any smokeless tobacco product unless the product package bears, in accordance with the requirements of this Act, one of the following labels:

''WARNING: This product can cause mouth cancer.

''WARNING: This product can cause gum disease and tooth loss.

''WARNING: This product is not a safe alternative to cigarettes.

''WARNING: Smokeless tobacco is addictive.

''(2) Each label statement required by paragraph (1) shall be—

''(A) located on the 2 principal display panels of the package, and each label statement shall comprise at least 30 percent of each such display panel; and

''(B) in 17-point conspicuous and legible type and in black text on a white background, or white text on a black background, in a manner that contrasts by typography, layout, or color, with all other printed material on the package, in an alternating fashion under the plan submitted under subsection (b)(3), except that if the text of a label statement would occupy more than 70 percent of the area specified by subparagraph (A), such text may appear in a smaller type size, so long as at least 60 percent of such warning area is occupied by the label statement.

''(3) The label statements required by paragraph (1) shall be introduced by each tobacco product manufacturer, packager, importer, distributor, or retailer of smokeless tobacco products concurrently into the distribution chain of such products.

''(4) The provisions of this subsection do not apply to a tobacco product manufacturer or distributor of any smokeless tobacco product that does not manufacture, package, or import smokeless tobacco products for sale or distribution within the United States.

''(5) A retailer of smokeless tobacco products shall not be in violation of this subsection for packaging that—

''(A) contains a warning label;

''(B) is supplied to the retailer by a license- or permit-holding tobacco product manufacturer, importer, or distributor; and

''(C) is not altered by the retailer in a way that is material to the requirements of this subsection.

''(b) REQUIRED LABELS.—

''(1) It shall be unlawful for any tobacco product manufacturer, packager, importer, distributor, or retailer of smokeless tobacco products to advertise or cause to be advertised within the United States any smokeless tobacco product unless its advertising bears, in accordance with the requirements of this section, one of the labels specified in subsection (a).

''(2)(A) Each label statement required by subsection (a) in smokeless tobacco advertising shall comply with the standards set forth in this paragraph.

''(B) For press and poster advertisements, each such statement and (where applicable) any required statement relating to tar, nicotine, or other constituent yield shall comprise at least 20 percent of the area of the advertisement.

''(C) The word 'WARNING' shall appear in capital letters, and each label statement shall appear in conspicuous and legible type.

''(D) The text of the label statement shall be black on a white background, or white on a black background, in an alternating fashion under the plan submitted under paragraph (3).

''(E) The label statements shall be enclosed by a rectangular border that is the same color as the letters of the statements and that is the width of the first downstroke of the capital 'W' of the word 'WARNING' in the label statements.

''(F) The text of such label statements shall be in a typeface pro rata to the following requirements: 45-point type for a whole-page broadsheet newspaper advertisement; 39-point type for a half-page broadsheet newspaper advertisement; 39-point type for a whole-page tabloid newspaper advertisement; 27-point type for a half-page tabloid newspaper advertisement; 31.5-point type for a double page spread magazine or whole-page magazine advertisement; 22.5-point type for a 28 centimeter by 3 column advertisement; and 15-point type for a 20 centimeter by 2 column advertisement.

''(G) The label statements shall be in English, except that—

''(i) in the case of an advertisement that appears in a newspaper, magazine, periodical, or other publication that is not in English, the statements shall appear in the predominant language of the publication; and

''(ii) in the case of any other advertisement that is not in English, the statements shall appear in the same language as that principally used in the advertisement.

''(3)(A) The label statements specified in subsection (a)(1) shall be randomly displayed in each 12-month period, in as equal a number of times as is possible on each brand of the product and be randomly distributed in all areas of the United States in which the product is marketed in accordance with a plan submitted by the tobacco product manufacturer, importer, distributor, or retailer and approved by the Secretary.

''(B) The label statements specified in subsection (a)(1) shall be rotated quarterly in alternating sequence in advertisements for each brand of smokeless tobacco product in accordance with a plan submitted by the tobacco product manufacturer, importer, distributor, or retailer to, and approved by, the Secretary.

''(C) The Secretary shall review each plan submitted under subparagraphs (A) and (B) and approve it if the plan—

''(i) will provide for the equal distribution and display on packaging and the rotation required in advertising under this subsection; and

''(ii) assures that all of the labels required under this section will be displayed by the tobacco product manufacturer, importer, distributor, or retailer at the same time.

''(D) This paragraph applies to a retailer only if that retailer is responsible for or directs the label statements under this section, unless the retailer displays, in a location open to the public, an advertisement that does not contain a warning label or has been altered by the retailer in a way that is material to the requirements of this subsection.

''(4) The Secretary may, through a rulemaking under section 553 of title 5, United States Code, adjust the format and type sizes for the label statements required by this section; the text, format, and type sizes of any required tar, nicotine yield, or other constituent disclosures; or the text, format, and type sizes for any other disclosures required under the Federal Food, Drug, and Cosmetic Act. The text of any such label statements or disclosures shall be required to appear only within the 20 percent area of advertisements provided by paragraph (2). The Secretary shall promulgate regulations which provide for adjustments in the format and type sizes of any text required to appear in such area to ensure that the total text required to appear by law will fit within such area.

''(c) TELEVISION AND RADIO ADVERTISING.—It is unlawful to advertise smokeless tobacco on any medium of electronic communications subject to the jurisdiction of the Federal Communications Commission.''.

(b) EFFECTIVE DATE.—The amendment made by subsection (a) shall take effect 12 months after the date of enactment of this Act. Such effective date shall be with respect to the date of manufacture, provided that, in any case, beginning 30 days after such effective date, a manufacturer shall not introduce into the domestic commerce of the United States any product, irrespective of the date of manufacture, that is not in conformance with section 3 of the Comprehensive Smokeless Tobacco Health Education Act of 1986 (15 U.S.C. 4402), as amended by subsection (a).

SEC. 205. AUTHORITY TO REVISE SMOKELESS TOBACCO PRODUCT WARNING LABEL STATEMENTS.

(a) IN GENERAL.—Section 3 of the Comprehensive Smokeless Tobacco Health Education Act of 1986 (15 U.S.C. 4402), as amended by section 204, is further amended by adding at the end the following:

''(d) AUTHORITY TO REVISE WARNING LABEL STATEMENTS.—The Secretary may, by a rulemaking conducted under section 553 of title 5, United States Code, adjust the format, type size, and text of any of the label requirements, require color graphics to accompany the text, increase the required label area from 30 percent up to 50 percent of the front and rear panels of the package, or establish the format, type size, and text of any other disclosures required under the Federal Food, Drug, and Cosmetic Act, if the Secretary finds that such a change would promote greater public understanding of the risks associated with the use of smokeless tobacco products.''.

(b) PREEMPTION.—Section 7(a) of the Comprehensive Smokeless Tobacco Health Education Act of 1986 (15 U.S.C. 4406(a)) is amended by striking ''No'' and inserting ''Except as provided in the Family Smoking Prevention and Tobacco Control Act (and the amendments made by that Act), no''.

SEC. 206. TAR, NICOTINE, AND OTHER SMOKE CONSTITUENT DISCLOSURE TO THE PUBLIC.

Section 4 of the Federal Cigarette Labeling and Advertising Act (15 U.S.C. 1333), as amended by sections 201 and 202, is further amended by adding at the end the following:

''(e) TAR, NICOTINE, AND OTHER SMOKE CONSTITUENT DISCLOSURE.—

''(1) IN GENERAL.—The Secretary shall, by a rulemaking conducted under section 553 of title 5, United States Code, determine (in the Secretary's sole discretion) whether cigarette and other tobacco product manufacturers shall be required to include in the area of each cigarette advertisement specified by subsection (b) of this section, or on the package label, or both, the tar and nicotine yields of the advertised or packaged brand. Any such disclosure shall be in accordance with the methodology established under such regulations, shall conform to the type size requirements of subsection (b) of this section, and shall appear within the area specified in subsection (b) of this section.

''(2) RESOLUTION OF DIFFERENCES.—Any differences between the requirements established by the Secretary under paragraph (1) and tar and nicotine yield reporting requirements established by the Federal Trade Commission shall be resolved by a memorandum of understanding between the Secretary and the Federal Trade Commission.

''(3) CIGARETTE AND OTHER TOBACCO PRODUCT CONSTITUENTS.—In addition to the disclosures required by paragraph (1), the Secretary may, under a rulemaking conducted under section 553 of title 5, United States Code, prescribe disclosure requirements regarding the level of any cigarette or other tobacco product constituent including any smoke constituent. Any such disclosure may be required if the Secretary determines that disclosure would be of benefit to the public health, or otherwise would increase consumer awareness of the health consequences of the use of tobacco products, except that no such prescribed disclosure shall be required on the face of any cigarette package or advertisement. Nothing in this section shall prohibit the Secretary from requiring such prescribed disclosure through a cigarette or other tobacco product package or advertisement insert, or by any other means under the Federal Food, Drug, and Cosmetic Act.

''(4) RETAILERS.—This subsection applies to a retailer only if that retailer is responsible for or directs the label statements required under this section.''.

TITLE III—PREVENTION OF ILLICIT TRADE IN TOBACCO PRODUCTS

SEC. 301. LABELING, RECORDKEEPING, RECORDS INSPECTION.

Chapter IX of the Federal Food, Drug, and Cosmetic Act, as added by section 101, is further amended by adding at the end the following:

''SEC. 920. LABELING, RECORDKEEPING, RECORDS INSPECTION.

''(a) ORIGIN LABELING.—

''(1) REQUIREMENT.—Beginning 1 year after the date of enactment of the Family Smoking Prevention and Tobacco Control Act, the label, packaging, and shipping containers of tobacco products other than cigarettes for introduction or delivery for introduction into interstate commerce in the United States shall bear the statement 'sale only allowed in the United States'. Beginning 15 months after the issuance of the regulations required by section 4(d) of the Federal Cigarette Labeling and Advertising Act (15 U.S.C. 1333), as amended by section 201 of Family Smoking Prevention and Tobacco Control Act, the label, packaging, and shipping containers of cigarettes for introduction or delivery for introduction into interstate commerce in the United States shall bear the statement 'Sale only allowed in the United States'.

''(2) EFFECTIVE DATE.—The effective date specified in paragraph (1) shall be with respect to the date of manufacture, provided that, in any case, beginning 30 days after such effective date, a manufacturer shall not introduce into the domestic commerce of the United States any product, irrespective of the date of manufacture, that is not in conformance with such paragraph.

''(b) REGULATIONS CONCERNING RECORDKEEPING FOR TRACKING AND TRACING.—

''(1) IN GENERAL.—The Secretary shall promulgate regulations regarding the establishment and maintenance of records by any person who manufactures, processes, transports, distributes, receives, packages, holds, exports, or imports tobacco products.

''(2) INSPECTION.—In promulgating the regulations described in paragraph (1), the Secretary shall consider which records are needed for inspection to monitor the movement of tobacco products from the point of manufacture through distribution to retail outlets to assist in investigating potential illicit trade, smuggling, or counterfeiting of tobacco products.

''(3) CODES.—The Secretary may require codes on the labels of tobacco products or other designs or devices for the purpose of tracking or tracing the tobacco product through the distribution system.

''(4) SIZE OF BUSINESS.—The Secretary shall take into account the size of a business in promulgating regulations under this section.

''(5) RECORDKEEPING BY RETAILERS.—The Secretary shall not require any retailer to maintain records relating to individual purchasers of tobacco products for personal consumption.

''(c) RECORDS INSPECTION.—If the Secretary has a reasonable belief that a tobacco product is part of an illicit trade or smuggling or is a counterfeit product, each person who manufactures, processes, transports, distributes, receives, holds, packages, exports, or imports tobacco products shall, at the request of an officer or employee duly designated by the Secretary, permit such officer or employee, at reasonable times and within reasonable limits and in a reasonable manner, upon the presentation of appropriate credentials and a written notice to such person, to have access to and copy all records (including financial records) relating to such article that are needed to assist the Secretary in investigating potential illicit trade, smuggling, or counterfeiting of tobacco products. The Secretary shall not authorize an officer or employee of the government of any of the several States to exercise authority under the preceding sentence on Indian country without the express written consent of the Indian tribe involved.

''(d) KNOWLEDGE OF ILLEGAL TRANSACTION.—

''(1) NOTIFICATION.—If the manufacturer or distributor of a tobacco product has knowledge which reasonably supports the conclusion that a tobacco product manufactured or distributed by such manufacturer or distributor that has left the control of such person may be or has been—

''(A) imported, exported, distributed, or offered for sale in interstate commerce by a person without paying duties or taxes required by law; or

''(B) imported, exported, distributed, or diverted for possible illicit marketing,

the manufacturer or distributor shall promptly notify the Attorney General and the Secretary of the Treasury of such knowledge.

''(2) KNOWLEDGE DEFINED.—For purposes of this subsection, the term 'knowledge' as applied to a manufacturer or distributor means—

''(A) the actual knowledge that the manufacturer or distributor had; or

''(B) the knowledge which a reasonable person would have had under like circumstances or which would have been obtained upon the exercise of due care.

''(e) CONSULTATION.—In carrying out this section, the Secretary shall consult with the Attorney General of the United States and the Secretary of the Treasury, as appropriate.''.

SEC. 302. STUDY AND REPORT.

(a) STUDY.—The Comptroller General of the United States shall conduct a study of cross-border trade in tobacco products to—

(1) collect data on cross-border trade in tobacco products, including illicit trade and trade of counterfeit tobacco products and make recommendations on the monitoring of such trade;

(2) collect data on cross-border advertising (any advertising intended to be broadcast, transmitted, or distributed from the United States to another country) of tobacco products and make recommendations on how to prevent or eliminate, and what technologies could help facilitate the elimination of, cross-border advertising; and

(3) collect data on the health effects (particularly with respect to individuals under 18 years of age) resulting from cross-border trade in tobacco products, including the health effects resulting from—

(A) the illicit trade of tobacco products and the trade of counterfeit tobacco products; and

(B) the differing tax rates applicable to tobacco products.

(b) REPORT.—Not later than 18 months after the date of enactment of this Act, the Comptroller General of the United States shall submit to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives a report on the study described in subsection (a).

(c) DEFINITION.—In this section:

(1) The term ''cross-border trade'' means trade across a border of the United States, a State or Territory, or Indian country.

(2) The term ''Indian country'' has the meaning given to such term in section 1151 of title 18, United States Code.

(3) The terms ''State'' and ''Territory'' have the meanings given to those terms in section 201 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321).

DIVISION B—FEDERAL RETIREMENT REFORM ACT

SEC. 100. SHORT TITLE; TABLE OF CONTENTS.

(a) SHORT TITLE.—This division may be cited as the ''Federal Retirement Reform Act of 2009''.

(b) TABLE OF CONTENTS.—The table of contents for this division is as follows:

TITLE I—PROVISIONS RELATING TO FEDERAL EMPLOYEES RETIREMENT

SEC. 101. SHORT TITLE.

This title may be cited as the ''Thrift Savings Plan Enhancement Act of 2009''.

SEC. 102. AUTOMATIC ENROLLMENTS AND IMMEDIATE EMPLOYING AGENCY CONTRIBUTIONS.

(a) IN GENERAL.—Section 8432(b) of title 5, United States Code, is amended by striking paragraphs (2) through (4) and inserting the following:

''(2)(A) The Executive Director shall by regulation provide for an eligible individual to be automatically enrolled to make contributions under subsection (a) at the default percentage of basic pay.

''(B) For purposes of this paragraph, the default percentage shall be equal to 3 percent or such other percentage, not less than 2 percent nor more than 5 percent, as the Board may prescribe.

''(C) The regulations shall include provisions under which any individual who would otherwise be automatically enrolled in accordance with subparagraph (A) may—

''(i) modify the percentage or amount to be contributed pursuant to automatic enrollment, effective not later than the first full pay period following receipt of the election by the appropriate processing entity; or

''(ii) decline automatic enrollment altogether.

''(D)(i) Except as provided in clause (ii), for purposes of this paragraph, the term 'eligible individual' means any individual who, after any regulations under subparagraph (A) first take effect, is appointed, transferred, or reappointed to a position in which that individual becomes eligible to contribute to the Thrift Savings Fund.

''(ii) Members of the uniformed services shall not be eligible individuals for purposes of this paragraph.

''(E) Sections 8351(a)(1), 8440a(a)(1), 8440b(a)(1), 8440c(a)(1), 8440d(a)(1), and 8440e(a)(1) shall be applied in a manner consistent with the purposes of this paragraph.''.

(b) TECHNICAL AMENDMENT.—Section 8432(b)(1) of title 5, United States Code, is amended by striking the parenthetical matter in subparagraph (B).

SEC. 103. QUALIFIED ROTH CONTRIBUTION PROGRAM.

(a) IN GENERAL.—Subchapter III of chapter 84 of title 5, United States Code, is amended by inserting after section 8432c the following:

''§ 8432d. Qualified Roth contribution program

''(a) DEFINITIONS.—For purposes of this section—

''(1) the term 'qualified Roth contribution program' means a program described in paragraph (1) of section 402A(b) of the Internal Revenue Code of 1986 which meets the requirements of paragraph (2) of such section; and

''(2) the terms 'designated Roth contribution' and 'elective deferral' have the meanings given such terms in section 402A of the Internal Revenue Code of 1986.

''(b) AUTHORITY TO ESTABLISH.—The Executive Director shall by regulation provide for the inclusion in the Thrift Savings Plan of a qualified Roth contribution program, under such terms and conditions as the Board may prescribe.

''(c) REQUIRED PROVISIONS.—The regulations under subsection (b) shall include—

''(1) provisions under which an election to make designated Roth contributions may be made—

''(A) by any individual who is eligible to make contributions under section 8351, 8432(a), 8440a, 8440b, 8440c, 8440d, or 8440e; and

''(B) by any individual, not described in subparagraph (A), who is otherwise eligible to make elective deferrals under the Thrift Savings Plan;

''(2) any provisions which may, as a result of enactment of this section, be necessary in order to clarify the meaning of any reference to an 'account' made in section 8432(f), 8433, 8434(d), 8435, 8437, or any other provision of law; and

''(3) any other provisions which may be necessary to carry out this section.''.

(b) CLERICAL AMENDMENT.—The analysis for chapter 84 of title 5, United States Code, is amended by inserting after the item relating to section 8432c the following:

''8432d. Qualified Roth contribution program.''.

SEC. 104. AUTHORITY TO ESTABLISH MUTUAL FUND WINDOW.

(a) IN GENERAL.—Section 8438(b)(1) of title 5, United States Code, is amended—

(1) in subparagraph (D), by striking ''and'' at the end;

(2) in subparagraph (E), by striking the period and inserting ''; and''; and

(3) by adding after subparagraph (E) the following:

''(F) a service that enables participants to invest in mutual funds, if the Board authorizes the mutual fund window under paragraph (5).''.

(b) REQUIREMENTS.—Section 8438(b) of title 5, United States Code, is amended by adding at the end the following:

''(5)(A) The Board may authorize the addition of a mutual fund window under the Thrift Savings Plan if the Board determines that such addition would be in the best interests of participants.

''(B) The Board shall ensure that any expenses charged for use of the mutual fund window are borne solely by the participants who use such window.

''(C) The Board may establish such other terms and conditions for the mutual fund window as the Board considers appropriate to protect the interests of participants, including requirements relating to risk disclosure.

''(D) The Board shall consult with the Employee Thrift Advisory Council (established under section 8473) before authorizing the addition of a mutual fund window or establishing a service that enables participants to invest in mutual funds.''.

(c) TECHNICAL AND CONFORMING AMENDMENT.—Section 8438(d)(1) of title 5, United States Code, is amended by inserting ''and options'' after ''investment funds''.

SEC. 105. REPORTING REQUIREMENTS.

(a) ANNUAL REPORT.—The Board shall, not later than June 30 of each year, submit to Congress an annual report on the operations of the Thrift Savings Plan. Such report shall include, for the prior calendar year, information on the number of participants as of the last day of such prior calendar year, the median balance in participants' accounts as of such last day, demographic information on participants, the percentage allocation of amounts among investment funds or options, the status of the development and implementation of the mutual fund window, the diversity demographics of any company, investment adviser, or other entity retained to invest and manage the assets of the Thrift Savings Fund, and such other information as the Board considers appropriate. A copy of each annual report under this subsection shall be made available to the public through an Internet website.

(b) REPORTING OF FEES AND OTHER INFORMATION.—

(1) IN GENERAL.—The Board shall include in the periodic statements provided to participants under section 8439(c) of title 5, United States Code, the amount of the investment management fees, administrative expenses, and any other fees or expenses paid with respect to each investment fund and option under the Thrift Savings Plan. Any such statement shall also provide a statement notifying participants as to how they may access the annual report described in subsection (a), as well as any other information concerning the Thrift Savings Plan that might be useful.

(2) USE OF ESTIMATES.—For purposes of providing the information required under this subsection, the Board may provide a reasonable and representative estimate of any fees or expenses described in paragraph (1) and shall indicate any such estimate as being such an estimate. Any such estimate shall be based on the previous year's experience.

(c) DEFINITIONS.—For purposes of this section—

(1) the term ''Board'' has the meaning given such term by 8401(5) of title 5, United States Code;

(2) the term ''participant'' has the meaning given such term by section 8471(3) of title 5, United States Code; and

(3) the term ''account'' means an account established under section 8439 of title 5, United States Code.

SEC. 106. ACKNOWLEDGMENT OF RISK.

(a) IN GENERAL.—Section 8439(d) of title 5, United States Code, is amended—

(1) by striking the matter after ''who elects to invest in'' and before ''shall sign an acknowledgment'' and inserting ''any investment fund or option under this chapter, other than the Government Securities Investment Fund,''; and

(2) by striking ''either such Fund'' and inserting ''any such fund or option''.

(b) COORDINATION WITH PROVISIONS RELATING TO FIDUCIARY RESPONSIBILITIES, LIABILITIES, AND PENALTIES.—Section 8477(e)(1)(C) of title 5, United States Code, is amended—

(1) by redesignating subparagraph (C) as subparagraph (C)(i); and

(2) by adding at the end the following:

''(ii) A fiduciary shall not be liable under subparagraph (A), and no civil action may be brought against a fiduciary—

''(I) for providing for the automatic enrollment of a participant in accordance with section 8432(b)(2)(A);

''(II) for enrolling a participant in a default investment fund in accordance with section 8438(c)(2); or

''(III) for allowing a participant to invest through the mutual fund window or for establishing restrictions applicable to participants' ability to invest through the mutual fund window.''.

SEC. 107. SUBPOENA AUTHORITY.

(a) IN GENERAL.—Chapter 84 of title 5, United States Code, is amended by inserting after section 8479 the following:

''§ 8480. Subpoena authority

''(a) In order to carry out the responsibilities specified in this subchapter and subchapter III of this chapter, the Executive Director may issue subpoenas commanding each person to whom the subpoena is directed to produce designated books, documents, records, electronically stored information, or tangible materials in the possession or control of that individual.

''(b) Notwithstanding any Federal, State, or local law, any person, including officers, agents, and employees, receiving a subpoena under this section, who complies in good faith with the subpoena and thus produces the materials sought, shall not be liable in any court of any State or the United States to any individual, domestic or foreign corporation or upon a partnership or other unincorporated association for such production.

''(c) When a person fails to obey a subpoena issued under this section, the district court of the United States for the district in which the investigation is conducted or in which the person failing to obey is found, shall on proper application issue an order directing that person to comply with the subpoena. The court may punish as contempt any disobedience of its order.

''(d) The Executive Director shall prescribe regulations to carry out subsection (a).''.

(b) TECHNICAL AND CONFORMING AMENDMENT.—The table of sections for chapter 84 of title 5, United States Code, is amended by inserting after the item relating to section 8479 the following:

''8480. Subpoena authority.''.

SEC. 108. AMOUNTS IN THRIFT SAVINGS FUNDS SUBJECT TO LEGAL PROCEEDINGS.

Section 8437(e)(3) of title 5, United States Code, is amended in the first sentence by striking ''or relating to the enforcement of a judgment for the physically, sexually, or emotionally abusing a child as provided under section 8467(a)'' and inserting ''the enforcement of an order for restitution under section 3663A of title 18, forfeiture under section 8432(g)(5) of this title, or an obligation of the Executive Director to make a payment to another person under section 8467 of this title''.

SEC. 109. ACCOUNTS FOR SURVIVING SPOUSES.

Section 8433(e) of title 5, United States Code, is amended—

(1) by inserting ''(1)'' after ''(e)''; and

(2) by adding at the end the following:

''(2) Notwithstanding section 8424(d), if an employee, Member, former employee, or former Member dies and has designated as sole or partial beneficiary his or her spouse at the time of death, or, if an employee, Member, former employee, or former Member, dies with no designated beneficiary and

is survived by a spouse, the spouse may maintain the portion of the employee's or Member's account to which the spouse is entitled in accordance with the following terms:

''(A) Subject to the limitations of subparagraph (B), the spouse shall have the same withdrawal options under subsection (b) as the employee or Member were the employee or Member living.

''(B) The spouse may not make withdrawals under subsection (g) or (h).

''(C) The spouse may not make contributions or transfers to the account.

''(D) The account shall be disbursed upon the death of the surviving spouse. A beneficiary or surviving spouse of a deceased spouse who has inherited an account is ineligible to maintain the inherited spousal account.

''(3) The Executive Director shall prescribe regulations to carry out this subsection.''.

SEC. 110. TREATMENT OF MEMBERS OF THE UNIFORMED SERVICES UNDER THE THRIFT SAVINGS PLAN.

(a) SENSE OF CONGRESS.—It is the sense of Congress that—

(1) members of the uniformed services should have a retirement system that is at least as generous as the one which is available to Federal civilian employees; and

(2) Federal civilian employees receive matching contributions from their employing agencies for their contributions to the Thrift Savings Fund, but the costs of requiring such a matching contribution from the Department of Defense could be significant.

(b) REPORTING REQUIREMENT.—Not later than 180 days after the date of the enactment of this Act, the Secretary of Defense shall report to Congress on—

(1) the cost to the Department of Defense of providing a matching payment with respect to contributions made to the Thrift Savings Fund by members of the Armed Forces;

(2) the effect that requiring such a matching payment would have on recruitment and retention; and

(3) any other information that the Secretary of Defense considers appropriate.

TITLE II—SPECIAL SURVIVOR INDEMNITY ALLOWANCE FOR SURVIVING SPOUSES OF ARMED FORCES MEMBERS

SEC. 201. INCREASE IN MONTHLY AMOUNT OF SPECIAL SURVIVOR INDEMNITY ALLOWANCE FOR WIDOWS AND WIDOWERS OF DECEASED MEMBERS OF THE ARMED FORCES AFFECTED BY REQUIRED SURVIVOR BENEFIT PLAN ANNUITY OFFSET FOR DEPENDENCY AND INDEMNITY COMPENSATION.

(a) PAYMENT AMOUNT PER FISCAL YEAR.—Paragraph (2) of section 1450(m) of title 10, United States Code, is amended—

(1) in subparagraph (E), by striking ''and'' after the semicolon; and

(2) by striking subparagraph (F) and inserting the following new subparagraphs:

''(F) for months during fiscal year 2014, $150;

''(G) for months during fiscal year 2015, $200;

''(H) for months during fiscal year 2016, $275; and

''(I) for months during fiscal year 2017, $310.''.

(b) DURATION.—Paragraph (6) of such section is amended—

(1) by striking ''February 28, 2016'' and inserting ''September 30, 2017''; and

(2) by striking ''March 1, 2016'' both places it appears and inserting ''October 1, 2017''.

SA 1248. Mrs. FEINSTEIN (for herself, Mr. BROWNBACK, and Ms. STABENOW) submitted an amendment intended to be proposed by her to the bill H.R. 1256, to protect the public health by providing the Food and Drug Administration with certain authority to regulate tobacco products, to amend title 5, United States Code, to make certain modifications in the Thrift Savings Plan, the Civil Service Retirement System, and the Federal Employees' Retirement System, and for other purposes; which was ordered to lie on the table; as follows:

At the appropriate place in division A, insert the following:

TITLE ____—REDUCING LUNG CANCER

SEC. ___1. SHORT TITLE.

This title may be cited as the ''Lung Cancer Mortality Reduction Act of 2009''.

SEC. ___2. SENSE OF THE SENATE CONCERNING INVESTMENT IN LUNG CANCER RESEARCH.

It is the sense of the Senate that—

(1) lung cancer mortality reduction should be made a national public health priority; and

(2) a comprehensive mortality reduction program coordinated by the Secretary of Health and Human Services is justified and necessary to adequately address and reduce lung cancer mortality.

SEC. ___3. LUNG CANCER MORTALITY REDUCTION PROGRAM.

(a) IN GENERAL.—Subpart 1 of part C of title IV of the Public Health Service Act (42 U.S.C. 285 et seq.) is amended by adding at the end the following:

''SEC. 417G. LUNG CANCER MORTALITY REDUCTION PROGRAM.

''(a) IN GENERAL.—Not later than 6 months after the date of enactment of the Lung Cancer Mortality Reduction Act of 2009, the Secretary, in consultation with the Secretary of Defense, the Secretary of Veterans Affairs, the Director of the National Institutes of Health, the Director of the Centers for Disease Control and Prevention, the Commissioner of the Food and Drug Administration, the Administrator of the Centers for Medicare & Medicaid Services, the Director of the National Center on Minority Health and Health Disparities, and other members of the Lung Cancer Advisory Board established under section ___6 of the Lung Cancer Mortality Reduction Act of 2009, shall implement a comprehensive program to achieve a 50 percent reduction in the mortality rate of lung cancer by 2016.

''(b) REQUIREMENTS.—The program implemented under subsection (a) shall include at least the following:

''(1) With respect to the National Institutes of Health—

''(A) a strategic review and prioritization by the National Cancer Institute of research grants to achieve the goal of the program in reducing lung cancer mortality;

''(B) the provision of funds to enable the Airway Biology and Disease Branch of the National Heart, Lung, and Blood Institute to expand its research programs to include predispositions to lung cancer, the interrelationship between lung cancer and other pulmonary and cardiac disease, and the diagnosis and treatment of these interrelationships;

''(C) the provision of funds to enable the National Institute of Biomedical Imaging and Bioengineering to expand its Quantum Grant Program and Image-Guided Interventions programs to expedite the development of computer assisted diagnostic, surgical, treatment, and drug testing innovations to reduce lung cancer mortality; and

''(D) the provision of funds to enable the National Institute of Environmental Health Sciences to implement research programs relative to lung cancer incidence.

''(2) With respect to the Food and Drug Administration—

''(A) the establishment of a lung cancer mortality reduction drug program under subchapter G of chapter V of the Federal Food, Drug, and Cosmetic Act; and

''(B) compassionate access activities under section 561 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360bbb).

''(3) With respect to the Centers for Disease Control and Prevention, the establishment of a lung cancer mortality reduction program under section 1511.

''(4) With respect to the Agency for Healthcare Research and Quality, the conduct of a biannual review of lung cancer screening, diagnostic and treatment protocols, and the issuance of updated guidelines.

''(5) The cooperation and coordination of all minority and health disparity programs within the Department of Health and Human Services to ensure that all aspects of the Lung Cancer Mortality Reduction Program adequately address the burden of lung cancer on minority and rural populations.

''(6) The cooperation and coordination of all tobacco control and cessation programs within agencies of the Department of Health and Human Services to achieve the goals of the Lung Cancer Mortality Reduction Program with particular emphasis on the coordination of drug and other cessation treatments with early detection protocols.

''(c) AUTHORIZATION OF APPROPRIATIONS.—There is authorized to be appropriated to carry out this section—

''(1) $25,000,000 for fiscal year 2010 for the activities described in subsection (b)(1)(B), and such sums as may be necessary for each of fiscal years 2011 through 2014;

''(2) $25,000,000 for fiscal year 2010 for the activities described in subsection (b)(1)(C), and such sums as may be necessary for each of fiscal years 2011 through 2014;

''(3) $10,000,000 for fiscal year 2010 for the activities described in subsection (b)(1)(D), and such sums as may be necessary for each of fiscal years 2011 through 2014; and

''(4) $15,000,000 for fiscal year 2010 for the activities described in subsection (b)(3), and such sums as may be necessary for each of fiscal years 2011 through 2014.''.

(b) FOOD, DRUG, AND COSMETIC ACT.—Chapter V of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351 et seq.) is amended by adding at the end the following:

''Subchapter G—Lung Cancer Mortality Reduction Programs

''SEC. 581. LUNG CANCER MORTALITY REDUCTION PROGRAM.

''(a) IN GENERAL.—The Secretary shall implement a program to provide incentives of the type provided for in subchapter B of this chapter for the development of chemoprevention drugs for precancerous conditions of the lung, drugs for targeted therapeutic treatments and vaccines for lung cancer, and new agents to curtail or prevent nicotine addiction. The Secretary shall model the program implemented under this section on the program provided for under subchapter B of this chapter with respect to certain drugs.

''(b) APPLICATION OF PROVISIONS.—The Secretary shall apply the provisions of subchapter B of this chapter to drugs, biological products, and devices for the prevention or treatment of lung cancer, including drugs, biological products, and devices for chemoprevention of precancerous conditions of the lungs, vaccination against the development of lung cancer, and therapeutic treatment for lung cancer.

''(c) BOARD.—The Board established under section ___6 of the Lung Cancer Mortality

Reduction Act of 2009 shall monitor the program implemented under this section.''.

(c) ACCESS TO UNAPPROVED THERAPIES.—Section 561(e) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360bbb(e)) is amended by inserting before the period the following: ''and shall include providing compassionate access to drugs, biological products, and devices under the program under section 581, with substantial consideration being given to whether the totality of information available to the Secretary regarding the safety and effectiveness of an investigational drug, as compared to the risk of morbidity and death from the disease, indicates that a patient may obtain more benefit than risk if treated with the drug, biological product, or device.''.

(d) CDC.—Title XV of the Public Health Service Act (42 U.S.C. 300k et seq.) is amended by adding at the end the following:

''SEC. 1511. LUNG CANCER MORTALITY REDUCTION PROGRAM.

''(a) IN GENERAL.—The Secretary shall establish and implement an early disease research and management program targeted at the high incidence and mortality rates among minority and low-income populations.

''(b) AUTHORIZATION OF APPROPRIATIONS.—There is authorized to be appropriated, such sums as may be necessary to carry out this section.''.

SEC. ___4. DEPARTMENT OF DEFENSE AND THE DEPARTMENT OF VETERANS AFFAIRS.

The Secretary of Defense and the Secretary of Veterans Affairs shall coordinate with the Secretary of Health and Human Services—

(1) in the development of the Lung Cancer Mortality Reduction Program under section 417E of part C of title IV of the Public Health Service Act, as amended by section ___4;

(2) in the implementation within the Department of Defense and the Department of Veterans Affairs of an early detection and disease management research program for military personnel and veterans whose smoking history and exposure to carcinogens during active duty service has increased their risk for lung cancer; and

(3) in the implementation of coordinated care programs for military personnel and veterans diagnosed with lung cancer.

SEC. ___5. LUNG CANCER ADVISORY BOARD.

(a) IN GENERAL.—The Secretary of Health and Human Services shall establish a Lung Cancer Advisory Board (referred to in this section as the ''Board'') to monitor the programs established under this title (and the amendments made by this title), and provide annual reports to Congress concerning benchmarks, expenditures, lung cancer statistics, and the public health impact of such programs.

(b) COMPOSITION.—The Board shall be composed of—

(1) the Secretary of Health and Human Services;

(2) the Secretary of Defense;

(3) the Secretary of Veterans Affairs; and

(4) two representatives each from the fields of—

(A) clinical medicine focused on lung cancer;

(B) lung cancer research;

(C) imaging;

(D) drug development; and

(E) lung cancer advocacy,

to be appointed by the Secretary of Health and Human Services.

SEC. ___6. AUTHORIZATION OF APPROPRIATIONS.

For the purpose of carrying out the programs under this title (and the amendments made by this title), there is authorized to be appropriated such sums as may be necessary for each of fiscal years 2010 through 2014.

SA 1249. Mrs. HAGAN submitted an amendment intended to be proposed by her to the bill H.R. 1256, to protect the public health by providing the Food and Drug Administration with certain authority to regulate tobacco products, to amend title 5, United States Code, to make certain modifications in the Thrift Savings Plan, the Civil Service Retirement System, and the Federal Employees' Retirement System, and for other purposes; which was ordered to lie on the table; as follows:

In section 907(a) of the Federal Food, Drug, and Cosmetic Act (as added by section 101), insert after paragraph (4) the following:

''(5) TECHNOLOGICAL FEASABILITY.—A tobacco product standard adopted under this section shall be based on a finding by the Secretary that technology is available to achieve the reductions required by such standard.''.

SA 1250. Mrs. HAGAN submitted an amendment intended to be proposed by her to the bill H.R. 1256, to protect the public health by providing the Food and Drug Administration with certain authority to regulate tobacco products, to amend title 5, United States Code, to make certain modifications in the Thrift Savings Plan, the Civil Service Retirement System, and the Federal Employees' Retirement System, and for other purposes; which was ordered to lie on the table; as follows:

In section 102(a)(2)(D), insert ''and other components and accessories necessary for the assembly of roll-your-own cigarettes'' after ''paper''.

SA 1251. Mrs. HAGAN submitted an amendment intended to be proposed by her to the bill H.R. 1256, to protect the public health by providing the Food and Drug Administration with certain authority to regulate tobacco products, to amend title 5, United States Code, to make certain modifications in the Thrift Savings Plan, the Civil Service Retirement System, and the Federal Employees' Retirement System, and for other purposes; which was ordered to lie on the table; as follows:

In section 900 of the Federal Food, Drug, and Cosmetic Act (as added by section 101) strike paragraph (16) and insert the following:

''(16) SMALL TOBACCO PRODUCT MANUFACTURER.—The term 'small tobacco product manufacturer' includes any farmer owned tobacco cooperative or a tobacco product manufacturer other than a cooperative that employs fewer than 350 employees. For purposes of determining the number of employees of a manufacturer under the preceding sentence, the employees of a manufacturer are deemed to include the employees of each entity that controls, is controlled by, or is under common control with such manufacture.''.

SA 1252. Mrs. HAGAN submitted an amendment intended to be proposed by her to the bill H.R. 1256, to protect the public health by providing the Food and Drug Administration with certain authority to regulate tobacco products, to amend title 5, United States Code, to make certain modifications in the Thrift Savings Plan, the Civil Service Retirement System, and the Federal Employees' Retirement System, and for other purposes; which was ordered to lie on the table; as follows:

In section 907(a)(4) of the Federal Food, Drug, and Cosmetic Act (as added by section 101(b)), strike clause (ii) of subparagraph (B) and all that follows through clause (v) of such subparagraph, and insert the following:

''(ii) provisions for the testing in a laboratory located in the United States (on a sample basis or, if necessary, on an individual basis) of the tobacco product;

''(iii) provisions for the measurement of the tobacco product characteristics of the tobacco product;

''(iv) provisions requiring that the results of each or of certain of the tests of the tobacco product required to be made under clause (ii) show that the tobacco product is in conformity with the portions of the standard for which the test or tests were required; and

''(v) a provision requiring that the sale and distribution of the tobacco product be restricted but only to the extent that the sale and distribution of a tobacco product may be restricted under a regulation under section 906(d);

''(C) shall require all tobacco product testing on domestic and foreign manufacturers' products to be performed in a laboratory located in the United States to ensure compliance with Federal law;

SA 1253. Mrs. HAGAN submitted an amendment intended to be proposed by her to the bill H.R. 1256, to protect the public health by providing the Food and Drug Administration with certain authority to regulate tobacco products, to amend title 5, United States Code, to make certain modifications in the Thrift Savings Plan, the Civil Service Retirement System, and the Federal Employees' Retirement System, and for other purposes; which was ordered to lie on the table; as follows:

In section 901(c)(2)(C) of the Federal Food, Drug, and Cosmetic Act (as added by section 101), strike '', other than activities by a manufacturer affecting production''.

SA 1254. Mrs. HAGAN submitted an amendment intended to be proposed by her to the bill H.R. 1256, to protect the public health by providing the Food and Drug Administration with certain authority to regulate tobacco products, to amend title 5, United States Code, to make certain modifications in the Thrift Savings Plan, the Civil Service Retirement System, and the Federal Employees' Retirement System, and for other purposes; which was ordered to lie on the table; as follows:

At the end of section 907 of the Federal Food, Drug, and Cosmetic Act (as added by section 101) add the following:

''(f) TECHNOLOGY REQUIRED TO MEET STANDARD.—It shall not be an act of infringement under section 271 of title 35, United States Code, for a tobacco product manufacturer to make use of a patented technology if such technology is used for the purpose of meeting any standard established under this section.''.

SA 1255. Ms. STABENOW (for herself, Mr. BROWNBACK, Ms. MIKULSKI, Mr. VOINOVICH, Mrs. SHAHEEN, Mr. BOND,

Mr. BURRIS, Mr. DURBIN, Mr. LEVIN, and Mr. BROWN) submitted an amendment intended to be proposed by her to the bill H.R. 1256, to protect the public health by providing the Food and Drug Administration with certain authority to regulate tobacco products, to amend title 5, United States Code, to make certain modifications in the Thrift Savings Plan, the Civil Service Retirement System, and the Federal Employees' Retirement System, and for other purposes; which was ordered to lie on the table; as follows:

At the appropriate place, insert the following:

DIVISION ____—DRIVE AMERICA FORWARD PROGRAM

SEC. __01. SHORT TITLE.

This division may be cited as the ''Drive America Forward Act of 2009''.

SEC. __02. DRIVE AMERICA FORWARD PROGRAM.

(a) ESTABLISHMENT.—There is established in the National Highway Traffic Safety Administration a voluntary program to be known as the ''Drive America Forward Program'' through which the Secretary, in accordance with this section and the regulations promulgated under subsection (d), shall—

(1) authorize the issuance of an electronic voucher, subject to the specifications set forth in subsection (c), to offset the purchase price or lease price for a qualifying lease of a new fuel efficient automobile upon the surrender of an eligible trade-in vehicle to a dealer participating in the Program;

(2) certify dealers for participation in the Program and require all participating dealers—

(A) to accept vouchers as provided in this section as partial payment or down payment for the purchase or qualifying lease of any new fuel efficient automobile offered for sale or lease by that dealer; and

(B) in accordance with subsection (c)(2), to transfer each eligible trade-in vehicle surrendered to the dealer under the Program to an entity for disposal;

(3) in consultation with the Secretary of the Treasury, make electronic payments to dealers for vouchers accepted by such dealers, in accordance with the regulations issued under subsection (d); and

(4) in consultation with the Secretary of the Treasury and the Inspector General of the Department of Transportation, establish and provide for the enforcement of measures to prevent and penalize fraud under the Program.

(b) QUALIFICATIONS FOR AND VALUE OF VOUCHERS.—A voucher issued under the Program shall have a value that may be applied to offset the purchase price or lease price for a qualifying lease of a new fuel efficient automobile as follows:

(1) $3,500 VALUE.—The voucher may be used to offset the purchase price or lease price of the new fuel efficient automobile by $3,500 if—

(A) the new fuel efficient automobile is a passenger automobile and the combined fuel economy value of such automobile is at least 4 miles per gallon higher than the combined fuel economy value of the eligible trade-in vehicle;

(B) the new fuel efficient automobile is a category 1 truck and the combined fuel economy value of such truck is at least 2 miles per gallon higher than the combined fuel economy value of the eligible trade-in vehicle;

(C) the new fuel efficient automobile is a category 2 truck that has a combined fuel economy value of at least 15 miles per gallon and—

(i) the eligible trade-in vehicle is a category 2 truck and the combined fuel economy value of the new fuel efficient automobile is at least 1 mile per gallon higher than the combined fuel economy value of the eligible trade-in vehicle; or

(ii) the eligible trade-in vehicle is a category 3 truck of model year 2001 or earlier; or

(D) the new fuel efficient automobile is a category 3 truck and the eligible trade-in vehicle is a category 3 truck of model year of 2001 or earlier and is of similar size or larger than the new fuel efficient automobile as determined in a manner prescribed by the Secretary.

(2) $4,500 VALUE.—The voucher may be used to offset the purchase price or lease price of the new fuel efficient automobile by $4,500 if—

(A) the new fuel efficient automobile is a passenger automobile and the combined fuel economy value of such automobile is at least 10 miles per gallon higher than the combined fuel economy value of the eligible trade-in vehicle;

(B) the new fuel efficient automobile is a category 1 truck and the combined fuel economy value of such truck is at least 5 miles per gallon higher than the combined fuel economy value of the eligible trade-in vehicle; or

(C) the new fuel efficient automobile is a category 2 truck that has a combined fuel economy value of at least 15 miles per gallon and the combined fuel economy value of such truck is at least 2 miles per gallon higher than the combined fuel economy value of the eligible trade-in vehicle and the eligible trade-in vehicle is a category 2 truck.

(c) PROGRAM SPECIFICATIONS.—

(1) LIMITATIONS.—

(A) GENERAL PERIOD OF ELIGIBILITY.—A voucher issued under the Program shall be used only for the purchase or qualifying lease of new fuel efficient automobiles that occur between—

(i) the date of the enactment of this Act; and

(ii) the day that is 1 year after the date on which the regulations promulgated under subsection (d) are implemented.

(B) NUMBER OF VOUCHERS PER PERSON AND PER TRADE-IN VEHICLE.—Not more than 1 voucher may be issued for a single person and not more than 1 voucher may be issued for the joint registered owners of a single eligible trade-in vehicle.

(C) NO COMBINATION OF VOUCHERS.—Only 1 voucher issued under the Program may be applied toward the purchase or qualifying lease of a single new fuel efficient automobile.

(D) CAP ON FUNDS FOR CATEGORY 3 TRUCKS.—Not more than 7.5 percent of the total funds made available for the Program shall be used for vouchers for the purchase or qualifying lease of category 3 trucks.

(E) COMBINATION WITH OTHER INCENTIVES PERMITTED.—The availability or use of a Federal, State, or local incentive or a State-issued voucher for the purchase or lease of a new fuel efficient automobile shall not limit the value or issuance of a voucher under the Program to any person otherwise eligible to receive such a voucher.

(F) NO ADDITIONAL FEES.—A dealer participating in the program may not charge a person purchasing or leasing a new fuel efficient automobile any additional fees associated with the use of a voucher under the Program.

(G) NUMBER AND AMOUNT.—The total number and value of vouchers issued under the Program may not exceed the amounts appropriated for such purpose.

(2) DISPOSITION OF ELIGIBLE TRADE-IN VEHICLES.—

(A) IN GENERAL.—For each eligible trade-in vehicle surrendered to a dealer under the Program, the dealer shall certify to the Secretary, in such manner as the Secretary shall prescribe by rule, that the dealer—

(i) has not and will not sell, lease, exchange, or otherwise dispose of the vehicle for use as an automobile in the United States or in any other country; and

(ii) will transfer the vehicle (including the engine block), in such manner as the Secretary prescribes, to an entity that will ensure that the vehicle—

(I) will be crushed or shredded within such period and in such manner as the Secretary prescribes; and

(II) has not been, and will not be, sold, leased, exchanged, or otherwise disposed of for use as an automobile in the United States or in any other country.

(B) SAVINGS PROVISION.—Nothing in subparagraph (A) may be construed to preclude a person who dismantles or disposes of the vehicle from—

(i) selling any parts of the disposed vehicle other than the engine block and drive train (unless the transmission, drive shaft, or rear end are sold as separate parts); or

(ii) retaining the proceeds from such sale.

(C) COORDINATION.—The Secretary shall coordinate with the Attorney General to ensure that the National Motor Vehicle Title Information System and other publicly accessible systems are appropriately updated on a timely basis to reflect the crushing or shredding of vehicles under this section and appropriate reclassification of the vehicles' titles. The commercial market shall also have electronic and commercial access to the vehicle identification numbers of vehicles that have been disposed of on a timely basis.

(d) REGULATIONS.—Notwithstanding the requirements of section 553 of title 5, United States Code, the Secretary shall promulgate final regulations to implement the Program not later than 30 days after the date of the enactment of this Act. Such regulations shall—

(1) provide for a means of certifying dealers for participation in the Program;

(2) establish procedures for the reimbursement of dealers participating in the Program to be made through electronic transfer of funds for both the amount of the vouchers and any reasonable administrative costs incurred by the dealer as soon as practicable but no longer than 10 days after the submission of a voucher for the new fuel efficient automobile to the Secretary;

(3) require the dealer to use the voucher in addition to any other rebate or discount advertised by the dealer or offered by the manufacturer for the new fuel efficient automobile and prohibit the dealer from using the voucher to offset any such other rebate or discount;

(4) require dealers to disclose to the person trading in an eligible trade-in vehicle the best estimate of the scrappage value of such vehicle and to permit the dealer to retain $50 of any amounts paid to the dealer for scrappage of the automobile as payment for any administrative costs to the dealer associated with participation in the Program;

(5) consistent with subsection (c)(2), establish requirements and procedures for the disposal of eligible trade-in vehicles and provide such information as may be necessary to entities engaged in such disposal to ensure that such vehicles are disposed of in accordance with such requirements and procedures, including—

(A) requirements for the removal and appropriate disposition of refrigerants, antifreeze, lead products, mercury switches, and such other toxic or hazardous vehicle components prior to the crushing or shredding of

an eligible trade-in vehicle, in accordance with rules established by the Secretary in consultation with the Administrator of the Environmental Protection Agency, and in accordance with other applicable Federal or State requirements;

(B) a mechanism for dealers to certify to the Secretary that each eligible trade-in vehicle will be transferred to an entity that will ensure that the vehicle is disposed of, in accordance with such requirements and procedures, and to submit the vehicle identification numbers of the vehicles disposed of and the new fuel efficient automobile purchased with each voucher; and

(C) a list of entities to which dealers may transfer eligible trade-in vehicles for disposal; and

(6) provide for the enforcement of the penalties described in subsection (e).

(e) ANTI-FRAUD PROVISIONS.—

(1) VIOLATION.—It shall be unlawful for any person to violate any provision under this section or any regulations issued pursuant to subsection (d) (other than by making a clerical error).

(2) PENALTIES.—Any person who commits a violation described in paragraph (1) shall be liable to the United States Government for a civil penalty of not more than $15,000 for each violation. In determining the amount of the civil penalty, the severity of the violation and the intent and history of the person committing the violation shall be taken into account.

(f) INFORMATION TO CONSUMERS AND DEALERS.—Not later than 30 days after the date of the enactment of this Act, and promptly upon the update of any relevant information, the Secretary, in consultation with the Administrator of the Environmental Protection Agency, shall make available on an Internet website and through other means determined by the Secretary information about the Program, including—

(1) how to determine if a vehicle is an eligible trade-in vehicle;

(2) how to participate in the Program, including how to determine participating dealers; and

(3) a comprehensive list, by make and model, of new fuel efficient automobiles meeting the requirements of the Program.

Once such information is available, the Secretary shall conduct a public awareness campaign to inform consumers about the Program and where to obtain additional information.

(g) RECORDKEEPING AND REPORT.—

(1) DATABASE.—The Secretary shall maintain a database of the vehicle identification numbers of all new fuel efficient vehicles purchased or leased and all eligible trade-in vehicles disposed of under the Program.

(2) REPORT ON EFFICACY OF THE PROGRAM.—Not later than 60 days after the termination date described in subsection (c)(1)(A)(ii), the Secretary shall submit a report to the Committee on Energy and Commerce of the House of Representatives and the Committee on Commerce, Science, and Transportation of the Senate describing the efficacy of the Program, including—

(A) a description of Program results, including—

(i) the total number and amount of vouchers issued for purchase or lease of new fuel efficient automobiles by manufacturer (including aggregate information concerning the make, model, model year) and category of automobile;

(ii) aggregate information regarding the make, model, model year, and manufacturing location of vehicles traded in under the Program; and

(iii) the location of sale or lease;

(B) an estimate of the overall increase in fuel efficiency in terms of miles per gallon, total annual oil savings, and total annual greenhouse gas reductions, as a result of the Program; and

(C) an estimate of the overall economic and employment effects of the Program.

(h) EXCLUSION OF VOUCHERS FROM INCOME.—

(1) FOR PURPOSES OF ALL FEDERAL AND STATE PROGRAMS.—A voucher issued under the Program shall not be regarded as income and shall not be regarded as a resource for the month of receipt of the voucher and the following 12 months, for purposes of determining the eligibility of the recipient of the voucher (or the recipient's spouse or other family or household members) for benefits or assistance, or the amount or extent of benefits or assistance, under any Federal or State program.

(2) FOR PURPOSES OF TAXATION.—A voucher issued under the Program shall not be considered as gross income for purposes of the Internal Revenue Code of 1986.

(i) DEFINITIONS.—As used in this section—

(1) the term ''passenger automobile'' means a passenger automobile, as defined in section 32901(a)(18) of title 49, United States Code, that has a combined fuel economy value of at least 22 miles per gallon;

(2) the term ''category 1 truck'' means a nonpassenger automobile, as defined in section 32901(a)(17) of title 49, United States Code, that has a combined fuel economy value of at least 18 miles per gallon, except that such term does not include a category 2 truck;

(3) the term ''category 2 truck'' means a large van or a large pickup, as categorized by the Secretary using the method used by the Environmental Protection Agency and described in the report entitled ''Light-Duty Automotive Technology and Fuel Economy Trends: 1975 through 2008'';

(4) the term ''category 3 truck'' means a work truck, as defined in section 32901(a)(19) of title 49, United States Code;

(5) the term ''combined fuel economy value'' means—

(A) with respect to a new fuel efficient automobile, the number, expressed in miles per gallon, centered below the words ''Combined Fuel Economy'' on the label required to be affixed or caused to be affixed on a new automobile pursuant to subpart D of part 600 of title 40, Code of Federal Regulations;

(B) with respect to an eligible trade-in vehicle, the equivalent of the number described in subparagraph (A), and posted under the words ''Estimated New EPA MPG'' and above the word ''Combined'' for vehicles of model year 1984 through 2007, or posted under the words ''New EPA MPG'' and above the word ''Combined'' for vehicles of model year 2008 or later on the fueleconomy.gov website of the Environmental Protection Agency for the make, model, and year of such vehicle; or

(C) with respect to an eligible trade-in vehicle manufactured between model years 1978 through 1984, the equivalent of the number described in subparagraph (A) as determined by the Secretary (and posted on the website of the National Highway Traffic Safety Administration) using data maintained by the Environmental Protection Agency for the make, model, and year of such vehicle;

(6) the term ''dealer'' means a person licensed by a State who engages in the sale of new automobiles to ultimate purchasers;

(7) the term ''eligible trade-in vehicle'' means an automobile or a work truck (as such terms are defined in section 32901(a) of title 49, United States Code) that, at the time it is presented for trade-in under this section—

(A) is in drivable condition;

(B) has been continuously insured consistent with the applicable State law and registered to the same owner for a period of not less than 1 year immediately prior to such trade-in;

(C) was manufactured less than 25 years before the date of the trade-in; and

(D) in the case of an automobile, has a combined fuel economy value of 18 miles per gallon or less;

(8) the term ''new fuel efficient automobile'' means an automobile described in paragraph (1), (2), (3), or (4)—

(A) the equitable or legal title of which has not been transferred to any person other than the ultimate purchaser;

(B) that carries a manufacturer's suggested retail price of $45,000 or less;

(C) that—

(i) in the case of passenger automobiles, category 1 trucks, or category 2 trucks, is certified to applicable standards under section 86.1811–04 of title 40, Code of Federal Regulations; or

(ii) in the case of category 3 trucks, is certified to the applicable vehicle or engine standards under section 86.1816–08, 86.007–11, or 86.008–10 of title 40, Code of Federal Regulations; and

(D) that has the combined fuel economy value of at least—

(i) 22 miles per gallon for a passenger automobile;

(ii) 18 miles per gallon for a category 1 truck; or

(iii) 15 miles per gallon for a category 2 truck;

(9) the term ''Program'' means the Drive America Forward Program established by this section;

(10) the term ''qualifying lease'' means a lease of an automobile for a period of not less than 5 years;

(11) the term ''scrappage value'' means the amount received by the dealer for a vehicle upon transferring title of such vehicle to the person responsible for ensuring the dismantling and destroying the vehicle;

(12) the term ''Secretary'' means the Secretary of Transportation acting through the National Highway Traffic Safety Administration;

(13) the term ''ultimate purchaser'' means, with respect to any new automobile, the first person who in good faith purchases such automobile for purposes other than resale; and

(14) the term ''vehicle identification number'' means the 17-character number used by the automobile industry to identify individual automobiles.

SEC. _03. REALLOCATION OF APPROPRIATIONS.

The Director of the Office of Management and Budget may reallocate not more than $4,000,000,000 from the amounts appropriated under the American Recovery and Reinvestment Act of 2009 (Public Law 111–5) to carry out the Drive America Forward Program established under this division if the Director notifies the Committee on Appropriations of the Senate and the Committee on Appropriations of the House of Representatives not less than 15 days before reallocating any such amounts.

SEC. _04. EMERGENCY DESIGNATION.

For purposes of House and Senate enforcement, this division is designated as an emergency requirement and necessary to meet emergency needs pursuant to—

(1) clause 10 of rule XXI of the Rules of the House of Representatives for the 111th Congress for purposes of pay-as-you-go principles; and

(2) section 403 of S. Con. Res. 13 (111th Congress), the concurrent resolution on the budget for fiscal year 2010.

SA 1256. Mr. SCHUMER (for Mr. LIEBERMAN (for himself, Ms. COLLINS, Mr. AKAKA, and Mr. VOINOVICH)) proposed an amendment to amendment

1247 proposed by Mr. DODD to the bill H.R. 1256, to protect the public health by providing the Food and Drug Administration with certain authority to regulate tobacco products, to amend title 5, United States Code, to make certain modifications in the Thrift Savings Plan, the Civil Service Retirement System, and the Federal Employees' Retirement System, and for other purposes; which was ordered to lie on the table; as follows:

At the end of title I of division B, add the following:

Subtitle B—Other Retirement-Related Provisions

SEC. 111. CREDIT FOR UNUSED SICK LEAVE.

(a) IN GENERAL.—Section 8415 of title 5, United States Code, is amended—

(1) by redesignating the second subsection (k) and subsection (l) as subsections (l) and (m), respectively; and

(2) in subsection (l) (as so redesignated by paragraph (1))—

(A) by striking ''(l) In computing'' and inserting ''(l)(1) In computing''; and

(B) by adding at the end the following:

''(2) Except as provided in paragraph (1), in computing an annuity under this subchapter, the total service of an employee who retires on an immediate annuity or who dies leaving a survivor or survivors entitled to annuity includes the days of unused sick leave to his credit under a formal leave system and for which days the employee has not received payment, except that these days will not be counted in determining average pay or annuity eligibility under this subchapter. For purposes of this subsection, in the case of any such employee who is excepted from subchapter I of chapter 63 under section 6301(2)(x) through (xiii), the days of unused sick leave to his credit include any unused sick leave standing to his credit when he was excepted from such subchapter.''.

(b) EXCEPTION FROM DEPOSIT REQUIREMENT.—Section 8422(d)(2) of title 5, United States Code, is amended by striking ''section 8415(k)'' and inserting ''paragraph (1) or (2) of section 8415(l)''.

(c) EFFECTIVE DATE.—The amendments made by this section shall apply with respect to annuities computed based on separations occurring on or after the date of enactment of this Act.

SEC. 112. LIMITED EXPANSION OF THE CLASS OF INDIVIDUALS ELIGIBLE TO RECEIVE AN ACTUARIALLY REDUCED ANNUITY UNDER THE CIVIL SERVICE RETIREMENT SYSTEM.

(a) IN GENERAL.—Section 8334(d)(2)(A)(i) of title 5, United States Code, is amended by striking ''October 1, 1990'' each place it appears and inserting ''March 1, 1991''.

(b) APPLICABILITY.—The amendment made by subsection (a) shall be effective with respect to any annuity, entitlement to which is based on a separation from service occurring on or after the date of enactment of this Act.

SEC. 113. COMPUTATION OF CERTAIN ANNUITIES BASED ON PART-TIME SERVICE.

(a) IN GENERAL.—Section 8339(p) of title 5, United States Code, is amended by adding at the end the following:

''(3) In the administration of paragraph (1)—

''(A) subparagraph (A) of such paragraph shall apply with respect to service performed before, on, or after April 7, 1986; and

''(B) subparagraph (B) of such paragraph—

''(i) shall apply with respect to that portion of any annuity which is attributable to service performed on or after April 7, 1986; and

''(ii) shall not apply with respect to that portion of any annuity which is attributable to service performed before April 7, 1986.''.

(b) APPLICABILITY.—The amendment made by subsection (a) shall be effective with respect to any annuity, entitlement to which is based on a separation from service occurring on or after the date of enactment of this Act.

SEC. 114. AUTHORITY TO DEPOSIT REFUNDS UNDER FERS.

(a) DEPOSIT AUTHORITY.—Section 8422 of title 5, United States Code, is amended by adding at the end the following:

''(i)(1) Each employee or Member who has received a refund of retirement deductions under this or any other retirement system established for employees of the Government covering service for which such employee or Member may be allowed credit under this chapter may deposit the amount received, with interest. Credit may not be allowed for the service covered by the refund until the deposit is made.

''(2) Interest under this subsection shall be computed in accordance with paragraphs (2) and (3) of section 8334(e) and regulations prescribed by the Office. The option under the third sentence of section 8334(e)(2) to make a deposit in one or more installments shall apply to deposits under this subsection.

''(3) For the purpose of survivor annuities, deposits authorized by this subsection may also be made by a survivor of an employee or Member.''.

(b) TECHNICAL AND CONFORMING AMENDMENTS.—

(1) DEFINITIONAL AMENDMENT.—Section 8401(19)(C) of title 5, United States Code, is amended by striking ''8411(f);'' and inserting ''8411(f) or 8422(i);''.

(2) CREDITING OF DEPOSITS.—Section 8422(c) of title 5, United States Code, is amended by adding at the end the following: ''Deposits made by an employee, Member, or survivor also shall be credited to the Fund.''.

(3) SECTION HEADING.—(A) The heading for section 8422 of title 5, United States Code, is amended to read as follows:

''§ 8422. Deductions from pay; contributions for other service; deposits''.

(B) The analysis for chapter 84 of title 5, United States Code, is amended by striking the item relating to section 8422 and inserting the following:

''8422. Deductions from pay; contributions for other service; deposits.''.

(4) RESTORATION OF ANNUITY RIGHTS.—The last sentence of section 8424(a) of title 5, United States Code, is amended by striking ''based.'' and inserting ''based, until the employee or Member is reemployed in the service subject to this chapter.''.

SEC. 115. RETIREMENT CREDIT FOR SERVICE OF CERTAIN EMPLOYEES TRANSFERRED FROM DISTRICT OF COLUMBIA SERVICE TO FEDERAL SERVICE.

(a) RETIREMENT CREDIT.—

(1) IN GENERAL.—Any individual who is treated as an employee of the Federal Government for purposes of chapter 83 or chapter 84 of title 5, United States Code, on or after the date of enactment of this Act who performed qualifying District of Columbia service shall be entitled to have such service included in calculating the individual's creditable service under sections 8332 or 8411 of title 5, United States Code, but only for purposes of the following provisions of such title:

(A) Sections 8333 and 8410 (relating to eligibility for annuity).

(B) Sections 8336 (other than subsections (d), (h), and (p) thereof) and 8412 (relating to immediate retirement).

(C) Sections 8338 and 8413 (relating to deferred retirement).

(D) Sections 8336(d), 8336(h), 8336(p), and 8414 (relating to early retirement).

(E) Section 8341 and subchapter IV of chapter 84 (relating to survivor annuities).

(F) Section 8337 and subchapter V of chapter 84 (relating to disability benefits).

(2) TREATMENT OF DETENTION OFFICER SERVICE AS LAW ENFORCEMENT OFFICER SERVICE.—Any portion of an individual's qualifying District of Columbia service which consisted of service as a detention officer under section 2604(2) of the District of Columbia Government Comprehensive Merit Personnel Act of 1978 (sec. 1–626.04(2), D.C. Official Code) shall be treated as service as a law enforcement officer under sections 8331(20) or 8401(17) of title 5, United States Code, for purposes of applying paragraph (1) with respect to the individual.

(3) SERVICE NOT INCLUDED IN COMPUTING AMOUNT OF ANY ANNUITY.—Qualifying District of Columbia service shall not be taken into account for purposes of computing the amount of any benefit payable out of the Civil Service Retirement and Disability Fund.

(b) QUALIFYING DISTRICT OF COLUMBIA SERVICE DEFINED.—In this section, ''qualifying District of Columbia service'' means any of the following:

(1) Service performed by an individual as a nonjudicial employee of the District of Columbia courts—

(A) which was performed prior to the effective date of the amendments made by section 11246(b) of the Balanced Budget Act of 1997; and

(B) for which the individual did not ever receive credit under the provisions of subchapter III of chapter 83 or chapter 84 of title 5, United States Code (other than by virtue of section 8331(1)(iv) of such title).

(2) Service performed by an individual as an employee of an entity of the District of Columbia government whose functions were transferred to the Pretrial Services, Parole, Adult Supervision, and Offender Supervision Trustee under section 11232 of the Balanced Budget Act of 1997—

(A) which was performed prior to the effective date of the individual's coverage as an employee of the Federal Government under section 11232(f) of such Act; and

(B) for which the individual did not ever receive credit under the provisions of subchapter III of chapter 83 or chapter 84 of title 5, United States Code (other than by virtue of section 8331(1)(iv) of such title).

(3) Service performed by an individual as an employee of the District of Columbia Public Defender Service—

(A) which was performed prior to the effective date of the amendments made by section 7(e) of the District of Columbia Courts and Justice Technical Corrections Act of 1998; and

(B) for which the individual did not ever receive credit under the provisions of subchapter III of chapter 83 or chapter 84 of title 5, United States Code (other than by virtue of section 8331(1)(iv) of such title).

(4) In the case of an individual who was an employee of the District of Columbia Department of Corrections who was separated from service as a result of the closing of the Lorton Correctional Complex and who was appointed to a position with the Bureau of Prisons, the District of Columbia courts, the Pretrial Services, Parole, Adult Supervision, and Offender Supervision Trustee, the United States Parole Commission, or the District of Columbia Public Defender Service, service performed by the individual as an employee of the District of Columbia Department of Corrections—

(A) which was performed prior to the effective date of the individual's coverage as an employee of the Federal Government; and

(B) for which the individual did not ever receive credit under the provisions of subchapter III of chapter 83 or chapter 84 of title 5, United States Code (other than by virtue of section 8331(1)(iv) of such title).

(c) CERTIFICATION OF SERVICE.—The Office of Personnel Management shall accept the certification of the appropriate personnel official of the government of the District of Columbia or other independent employing entity concerning whether an individual performed qualifying District of Columbia service and the length of the period of such service the individual performed.

SEC. 116. RETIREMENT TREATMENT OF CERTAIN SECRET SERVICE EMPLOYEES.

(a) DEFINITION.—In this section the term ''covered employee'' means an individual who—

(1) was hired as a member of the United States Secret Service Division during the period beginning on January 1, 1984 through December 31, 1986;

(2) has actively performed duties other than clerical for 10 or more years directly related to the protection mission of the United States Secret Service described under section 3056 of title 18, United States Code;

(3) is serving as a member of the United States Secret Service Division or the United States Secret Service Uniform Division (or any successor entity) on the effective date of this section; and

(4) files an election to be a covered employee under subsection (b)(1).

(b) ELECTION OF COVERAGE.—

(1) IN GENERAL.—Not later than 60 days after the date of enactment of this Act, an individual described under subsection (a)(1), (2), and (3) may file an election with the United States Secret Service to be a covered employee and to transition to the District of Columbia Police and Fire Fighter Retirement and Disability System.

(2) NOTIFICATION.—Not later than 30 days after the date of enactment of this Act, the Office of Personnel Management and the United States Secret Service shall notify each individual described under subsection (a)(1), (2), and (3) that the individual is qualified to file an election under paragraph (1).

(c) RETIREMENT COVERAGE CONVERSION.—

(1) IN GENERAL.—Not later than 180 days after the date of enactment of this Act, and in consultation with the Secretary of Homeland Security and the Thrift Savings Board, the Office of Personnel Management shall prescribe regulations to carry out the responsibilities of the Federal Government under this section. The regulations prescribed under this paragraph shall provide for transition of covered employees from the Federal Employees' Retirement System to the Civil Service Retirement System.

(2) TREATMENT OF COVERED EMPLOYEES.—

(A) ELECTION OF COVERAGE.—

(i) IN GENERAL.—If a covered employee files an election under subsection (b)(1), the covered employee shall, subject to clause (ii), be converted from the Federal Employees' Retirement System to the Civil Service Retirement System.

(ii) COVERAGE IN DISTRICT OF COLUMBIA RETIREMENT SYSTEM.—

(I) IN GENERAL.—Chapter 7 of title 5 of the District of Columbia Code shall apply with respect to a covered employee on the date on which the covered employee transitions to the Civil Service Retirement System.

(II) AUTHORIZATION FOR DISTRICT OF COLUMBIA.—The government of the District of Columbia shall provide for the coverage of covered employees in the District of Columbia Police and Fire Fighter Retirement and Disability System in accordance with this section.

(B) THRIFT SAVINGS PLAN.—A covered employee shall forfeit, under procedures prescribed by the Executive Director of the Federal Retirement Thrift Investment Board, all Thrift Savings Plan contributions and associated earnings made by an employing agency pursuant to section 8432(c) of title 5, United States Code. Any amounts remaining in the Thrift Savings Plan account of the covered employee may be transferred to a private account or the District of Columbia Police and Firefighter Retirement and Disability System.

(C) FORFEITURE OF SOCIAL SECURITY BENEFITS.—

(i) CONTRIBUTIONS.—Upon conversion into the Civil Service Retirement System, a covered employee shall forfeit all contributions made under title II of the Social Security Act while employed by the United States Secret Service. All forfeited funds shall remain in the Federal Old-Age and Survivors Insurance Trust Fund and the Federal Disability Insurance Trust Fund, as applicable .

(ii) BENEFITS.—A covered employee shall not be entitled to any benefit based on any contribution forfeited under clause (i).

(3) IMPLEMENT.—The Office of Personnel Management, the Department of Homeland Security, the Social Security Administration, and the Thrift Savings Board shall take such actions as necessary to provide for the implementation of this section.

(d) EFFECTIVE DATE.—

(1) IN GENERAL.—Except as provided under paragraph (2), this section shall take effect on the first day of the first applicable pay period that begins 180 days after the date of enactment of this Act.

(2) ELECTIONS AND IMPLEMENTATION.—Subsections (b) and (c)(1) and (3) shall take effect on the date of enactment of this Act.

TITLE _____—NON-FOREIGN AREA RETIREMENT EQUITY ASSURANCE

SEC. __01. SHORT TITLE.

This title may be cited as the ''Non-Foreign Area Retirement Equity Assurance Act of 2009'' or the ''Non-Foreign AREA Act of 2009''.

SEC. __02. EXTENSION OF LOCALITY PAY.

(a) LOCALITY-BASED COMPARABILITY PAYMENTS.—Section 5304 of title 5, United States Code, is amended—

(1) in subsection (f)(1), by striking subparagraph (A) and inserting the following:

''(A) each General Schedule position in the United States, as defined under section 5921(4), and its territories and possessions, including the Commonwealth of Puerto Rico and the Commonwealth of the Northern Mariana Islands, shall be included within a pay locality;'';

(2) in subsection (g)—

(A) in paragraph (2)—

(i) in subparagraph (A), by striking ''and'' after the semicolon;

(ii) in subparagraph (B) by striking the period and inserting ''; and''; and

(iii) by adding after subparagraph (B) the following:

''(C) positions under subsection (h)(1)(C) not covered by appraisal systems certified under section 5382; and''; and

(B) by adding at the end the following:

''(3) The applicable maximum under this subsection shall be level II of the Executive Schedule for positions under subsection (h)(1)(C) covered by appraisal systems certified under section 5307(d).''; and

(3) in subsection (h)(1)—

(A) in subparagraph (B) by striking ''and'' after the semicolon;

(B) by redesignating subparagraph (C) as subparagraph (D);

(C) by inserting after subparagraph (B) the following:

''(C) a Senior Executive Service position under section 3132 or 3151 or a senior level position under section 5376 stationed within the United States, but outside the 48 contiguous States and the District of Columbia in which the incumbent was an individual who on the day before the date of enactment of the Non-Foreign Area Retirement Equity Assurance Act of 2009 was eligible to receive a cost-of-living allowance under section 5941; and'';

(D) in clause (iv) in the matter following subparagraph (D), by inserting '', except for members covered by subparagraph (C)'' before the semicolon; and

(E) in clause (v) in the matter following subparagraph (D), by inserting '', except for members covered by subparagraph (C)'' before the semicolon.

(b) ALLOWANCES BASED ON LIVING COSTS AND CONDITIONS OF ENVIRONMENT.—Section 5941 of title 5, United States Code, is amended—

(1) in subsection (a), by adding after the last sentence ''Notwithstanding any preceding provision of this subsection, the cost-of-living allowance rate based on paragraph (1) shall be the cost-of-living allowance rate in effect on the date of enactment of the Non-Foreign Area Retirement Equity Assurance Act of 2009, except as adjusted under subsection (c).'';

(2) by redesignating subsection (b) as subsection (d); and

(3) by inserting after subsection (a) the following:

''(b) This section shall apply only to areas that are designated as cost-of-living allowance areas as in effect on December 31, 2009.

''(c)(1) The cost-of-living allowance rate payable under this section shall be adjusted on the first day of the first applicable pay period beginning on or after—

''(A) January 1, 2010; and

''(B) January 1 of each calendar year in which a locality-based comparability adjustment takes effect under section __04 (2) and (3) of the Non-Foreign Area Retirement Equity Assurance Act of 2009.

''(2)(A) In this paragraph, the term 'applicable locality-based comparability pay percentage' means, with respect to calendar year 2010 and each calendar year thereafter, the applicable percentage under section __04 (1), (2), or (3) of Non-Foreign Area Retirement Equity Assurance Act of 2009.

''(B) Each adjusted cost-of-living allowance rate under paragraph (1) shall be computed by—

''(i) subtracting 65 percent of the applicable locality-based comparability pay percentage from the cost-of-living allowance percentage rate in effect on December 31, 2009; and

''(ii) dividing the resulting percentage determined under clause (i) by the sum of—

''(I) one; and

''(II) the applicable locality-based comparability payment percentage expressed as a numeral.

''(3) No allowance rate computed under paragraph (2) may be less than zero.

''(4) Each allowance rate computed under paragraph (2) shall be paid as a percentage of basic pay (including any applicable locality-based comparability payment under section 5304 or similar provision of law and any applicable special rate of pay under section 5305 or similar provision of law).''.

SEC. __03. ADJUSTMENT OF SPECIAL RATES.

(a) IN GENERAL.—Each special rate of pay established under section 5305 of title 5, United States Code, and payable in an area designated as a cost-of-living allowance area under section 5941(a) of that title, shall be adjusted, on the dates prescribed by section __04 of this title, in accordance with regulations prescribed by the Director of the Office of Personnel Management under section __08 of this title.

(b) AGENCIES WITH STATUTORY AUTHORITY.—

(1) IN GENERAL.—Each special rate of pay established under an authority described under paragraph (2) and payable in a location designated as a cost-of-living allowance area under section 5941(a)(1) of title 5, United States Code, shall be adjusted in accordance with regulations prescribed by the applicable head of the agency that are consistent with the regulations issued by the Director of the Office of Personnel Management under subsection (a).

(2) STATUTORY AUTHORITY.—The authority referred to under paragraph (1), is any statutory authority that—

(A) is similar to the authority exercised under section 5305 of title 5, United States Code;

(B) is exercised by the head of an agency when the head of the agency determines it to be necessary in order to obtain or retain the services of persons specified by statute; and

(C) authorizes the head of the agency to increase the minimum, intermediate, or maximum rates of basic pay authorized under applicable statutes and regulations.

(c) TEMPORARY ADJUSTMENT.—Regulations issued under subsection (a) or (b) may provide that statutory limitations on the amount of such special rates may be temporarily raised to a higher level during the transition period described in section __04 ending on the first day of the first pay period beginning on or after January 1, 2012, at which time any special rate of pay in excess of the applicable limitation shall be converted to a retained rate under section 5363 of title 5, United States Code.

SEC. __04. TRANSITION SCHEDULE FOR LOCALITY-BASED COMPARABILITY PAYMENTS.

Notwithstanding any other provision of this title or section 5304 or 5304a of title 5, United States Code, in implementing the amendments made by this title, for each non-foreign area determined under section 5941(b) of that title, the applicable rate for the locality-based comparability adjustment that is used in the computation required under section 5941(c) of that title shall be adjusted effective on the first day of the first pay period beginning on or after January 1—

(1) in calendar year 2010, by using ⅓ of the locality pay percentage for the rest of United States locality pay area;

(2) in calendar year 2011, by using ⅔ of the otherwise applicable comparability payment approved by the President for each non-foreign area; and

(3) in calendar year 2012 and each subsequent year, by using the full amount of the applicable comparability payment approved by the President for each non-foreign area.

SEC. __05. SAVINGS PROVISION.

(a) SENSE OF CONGRESS.—It is the sense of Congress that—

(1) the application of this title to any employee should not result in a decrease in the take home pay of that employee;

(2) in calendar year 2012 and each subsequent year, no employee shall receive less than the Rest of the U.S. locality pay rate;

(3) concurrent with the surveys next conducted under the provisions of section 5304(d)(1)(A) of title 5, United States Code, beginning after the date of the enactment of this Act, the Bureau of Labor Statistics should conduct separate surveys to determine the extent of any pay disparity (as defined by section 5302 of that title) that may exist with respect to positions located in the State of Alaska, the State of Hawaii, and the United States territories, including American Samoa, Guam, Commonwealth of the Northern Mariana Islands, Commonwealth of Puerto Rico, and the United States Virgin Islands;

(4) if the surveys under paragraph (3) indicate that the pay disparity determined for the State of Alaska, the State of Hawaii, or any 1 of the United States territories including American Samoa, Guam, Commonwealth of the Northern Mariana Islands, Commonwealth of Puerto Rico, and the United States Virgin Islands exceeds the pay disparity determined for the locality which (for purposes of section 5304 of that title) is commonly known as the ''Rest of the United States'', the President's Pay Agent should take appropriate measures to provide that each such surveyed area be treated as a separate pay locality for purposes of that section; and

(5) the President's Pay Agent will establish 1 locality area for the entire State of Hawaii and 1 locality area for the entire State of Alaska.

(b) SAVINGS PROVISIONS.—

(1) IN GENERAL.—During the period described under section __04 of this title, an employee paid a special rate under 5305 of title 5, United States Code, who the day before the date of enactment of this Act was eligible to receive a cost-of-living allowance under section 5941 of title 5, United States Code, and who continues to be officially stationed in an allowance area, shall receive an increase in the employee's special rate consistent with increases in the applicable special rate schedule. For employees in allowance areas, the minimum step rate for any grade of a special rate schedule shall be increased at the time of an increase in the applicable locality rate percentage for the allowance area by not less than the dollar increase in the locality-based comparability payment for a non-special rate employee at the same minimum step provided under section __04 of this title, and corresponding increases shall be provided for all step rates of the given pay range.

(2) CONTINUATION OF COST OF LIVING ALLOWANCE RATE.—If an employee, who the day before the date of enactment of this Act was eligible to receive a cost-of-living allowance under section 5941 of title 5, United States Code, would receive a rate of basic pay and applicable locality-based comparability payment which is in excess of the maximum rate limitation set under section 5304(g) of title 5, United States Code, for his position (but for that maximum rate limitation) due to the operation of this title, the employee shall continue to receive the cost-of-living allowance rate in effect on December 31, 2009 without adjustment until—

(A) the employee leaves the allowance area or pay system; or

(B) the employee is entitled to receive basic pay (including any applicable locality-based comparability payment or similar supplement) at a higher rate,

but, when any such position becomes vacant, the pay of any subsequent appointee thereto shall be fixed in the manner provided by applicable law and regulation.

(3) LOCALITY-BASED COMPARABILITY PAYMENTS.—Any employee covered under paragraph (2) shall receive any applicable locality-based comparability payment extended under section __04 of this title which is not in excess of the maximum rate set under section 5304(g) of title 5, United States Code, for his position including any future increase to statutory pay limitations under 5318 of title 5, United States Code. Notwithstanding paragraph (2), to the extent that an employee covered under that paragraph receives any amount of locality-based comparability payment, the cost-of-living allowance rate under that paragraph shall be reduced accordingly, as provided under section 5941(c)(2)(B) of title 5, United States Code.

SEC. __06. APPLICATION TO OTHER ELIGIBLE EMPLOYEES.

(a) IN GENERAL.—

(1) DEFINITION.—In this subsection, the term ''covered employee'' means—

(A) any employee who—

(i) on the day before the date of enactment of this Act—

(I) was eligible to be paid a cost-of-living allowance under 5941 of title 5, United States Code; and

(II) was not eligible to be paid locality-based comparability payments under 5304 or 5304a of that title; or

(ii) on or after the date of enactment of this Act becomes eligible to be paid a cost-of-living allowance under 5941 of title 5, United States Code; or

(B) any employee who—

(i) on the day before the date of enactment of this Act—

(I) was eligible to be paid an allowance under section 1603(b) of title 10, United States Code;

(II) was eligible to be paid an allowance under section 1005(b) of title 39, United States Code;

(III) was employed by the Transportation Security Administration of the Department of Homeland Security and was eligible to be paid an allowance based on section 5941 of title 5, United States Code; or

(IV) was eligible to be paid under any other authority a cost-of-living allowance that is equivalent to the cost-of-living allowance under section 5941 of title 5, United States Code; or

(ii) on or after the date of enactment of this Act—

(I) becomes eligible to be paid an allowance under section 1603(b) of title 10, United States Code;

(II) becomes eligible to be paid an allowance under section 1005(b) of title 39, United States Code;

(III) is employed by the Transportation Security Administration of the Department of Homeland Security and becomes eligible to be paid an allowance based on section 5941 of title 5, United States Code; or

(IV) is eligible to be paid under any other authority a cost-of-living allowance that is equivalent to the cost-of-living allowance under section 5941 of title 5, United States Code.

(2) APPLICATION TO COVERED EMPLOYEES.—

(A) IN GENERAL.—Notwithstanding any other provision of law, for purposes of this title (including the amendments made by this title) any covered employee shall be treated as an employee to whom section 5941 of title 5, United States Code (as amended by section __02 of this title), and section __04 of this title apply.

(B) PAY FIXED BY STATUTE.—Pay to covered employees under section 5304 or 5304a of title 5, United States Code, as a result of the application of this title shall be considered to be fixed by statute.

(C) PERFORMANCE APPRAISAL SYSTEM.—With respect to a covered employee who is subject to a performance appraisal system no part of pay attributable to locality-based comparability payments as a result of the application of this title including section 5941 of title 5, United States Code (as amended by section __02 of this title), may be reduced on the basis of the performance of that employee.

(b) POSTAL EMPLOYEES IN NON-FOREIGN AREAS.—

(1) IN GENERAL.—Section 1005(b) of title 39, United States Code, is amended—

(A) by inserting ''(1)'' after ''(b)'';

(B) by striking ''Section 5941,'' and inserting ''Except as provided under paragraph (2), section 5941'';

(C) by striking ''For purposes of such section,'' and inserting ''Except as provided under paragraph (2), for purposes of section 5941 of that title,''; and

(D) by adding at the end the following:

''(2) On and after the date of enactment of the Non-Foreign Area Retirement Equity Assurance Act of 2009—

''(A) the provisions of that Act and section 5941 of title 5 shall apply to officers and employees covered by section 1003 (b) and (c) whose duty station is in a nonforeign area; and

''(B) with respect to officers and employees of the Postal Service (other than those officers and employees described under subparagraph (A)) of section __06(b)(2) of that Act shall apply.''.

(2) CONTINUATION OF COST OF LIVING ALLOWANCE.—

(A) IN GENERAL.—Notwithstanding any other provision of this title, any employee of the Postal Service (other than an employee covered by section 1003 (b) and (c) of title 39, United States Code, whose duty station is in a nonforeign area) who is paid an allowance under section 1005(b) of that title shall be treated for all purposes as if the provisions of this title (including the amendments made by this title) had not been enacted, except that the cost-of-living allowance rate paid to that employee—

(i) may result in the allowance exceeding 25 percent of the rate of basic pay of that employee; and

(ii) shall be the greater of—

(I) the cost-of-living allowance rate in effect on December 31, 2009 for the applicable area; or

(II) the applicable locality-based comparability pay percentage under section __04.

(B) RULE OF CONSTRUCTION.—Nothing in this title shall be construed to—

(i) provide for an employee described under subparagraph (A) to be a covered employee as defined under subsection (a); or

(ii) authorize an employee described under subparagraph (A) to file an election under section __07 of this title.

SEC. __07. ELECTION OF ADDITIONAL BASIC PAY FOR ANNUITY COMPUTATION BY EMPLOYEES.

(a) DEFINITION.—In this section the term ''covered employee'' means any employee—

(1) to whom section __04 applies;

(2) who is separated from service by reason of retirement under chapter 83 or 84 of title 5, United States Code, during the period of January 1, 2010, through December 31, 2012; and

(3) who files an election with the Office of Personnel Management under subsection (b).

(b) ELECTION.—

(1) IN GENERAL.—An employee described under subsection (a) (1) and (2) may file an election with the Office of Personnel Management to be covered under this section.

(2) DEADLINE.—An election under this subsection may be filed not later than December 31, 2012.

(c) COMPUTATION OF ANNUITY.—

(1) IN GENERAL.—Except as provided under paragraph (2), for purposes of the computation of an annuity of a covered employee any cost-of-living allowance under section 5941 of title 5, United States Code, paid to that employee during the first applicable pay period beginning on or after January 1, 2010 through the first applicable pay period ending on or after December 31, 2012, shall be considered basic pay as defined under section 8331(3) or 8401(4) of that title.

(2) LIMITATION.—The amount of the cost-of-living allowance which may be considered basic pay under paragraph (1) may not exceed the amount of the locality-based comparability payments the employee would have received during that period for the applicable pay area if the limitation under section __04 of this title did not apply.

(d) CIVIL SERVICE RETIREMENT AND DISABILITY RETIREMENT FUND.—

(1) EMPLOYEE CONTRIBUTIONS.—A covered employee shall pay into the Civil Service Retirement and Disability Retirement Fund—

(A) an amount equal to the difference between—

(i) employee contributions that would have been deducted and withheld from pay under section 8334 or 8422 of title 5, United States Code, during the period described under subsection (c) of this section if the cost-of-living allowances described under that subsection had been treated as basic pay under section 8331(3) or 8401(4) of title 5, United States Code; and

(ii) employee contributions that were actually deducted and withheld from pay under section 8334 or 8422 of title 5, United States Code, during that period; and

(B) interest as prescribed under section 8334(e) of title 5, United States Code, based on the amount determined under subparagraph (A).

(2) AGENCY CONTRIBUTIONS.—

(A) IN GENERAL.—The employing agency of a covered employee shall pay into the Civil Service Retirement and Disability Retirement Fund an amount for applicable agency contributions based on payments made under paragraph (1).

(B) SOURCE.—Amounts paid under this paragraph shall be contributed from the appropriation or fund used to pay the employee.

(3) REGULATIONS.—The Office of Personnel Management may prescribe regulations to carry out this section.

SEC. __08. REGULATIONS.

(a) IN GENERAL.—The Director of the Office of Personnel Management shall prescribe regulations to carry out this title, including—

(1) rules for special rate employees described under section __03;

(2) rules for adjusting rates of basic pay for employees in pay systems administered by the Office of Personnel Management when such employees are not entitled to locality-based comparability payments under section 5304 of title 5, United States Code, without regard to otherwise applicable statutory pay limitations during the transition period described in section __04 ending on the first day of the first pay period beginning on or after January 1, 2012; and

(3) rules governing establishment and adjustment of saved or retained rates for any employee whose rate of pay exceeds applicable pay limitations on the first day of the first pay period beginning on or after January 1, 2012.

(b) OTHER PAY SYSTEMS.—With the concurrence of the Director of the Office of Personnel Management, the administrator of a pay system not administered by the Office of Personnel Management shall prescribe regulations to carry out this title with respect to employees in such pay system, consistent with the regulations prescribed by the Office under subsection (a). With respect to employees not entitled to locality-based comparability payments under section 5304 of title 5, United States Code, regulations prescribed under this subsection may provide for special payments or adjustments for employees who were eligible to receive a cost-of-living allowance under section 5941 of that title on the date before the date of enactment of this Act.

SEC. __09. EFFECTIVE DATES.

(a) IN GENERAL.—Except as provided by subsection (b), this title (including the amendments made by this title) shall take effect on the date of enactment of this Act.

(b) LOCALITY PAY AND SCHEDULE.—The amendments made by section __02 and the provisions of section __04 shall take effect on the first day of the first applicable pay period beginning on or after January 1, 2010.

TITLE _____—PART-TIME REEMPLOYMENT OF ANNUITANTS

SEC. ___1. SHORT TITLE.

This title may be cited as the ''Part-Time Reemployment of Annuitants Act of 2009''.

SEC. ___2. PART-TIME REEMPLOYMENT.

(a) CIVIL SERVICE RETIREMENT SYSTEM.—Section 8344 of title 5, United States Code, is amended—

(1) by redesignating subsection (l) as subsection (m);

(2) by inserting after subsection (k) the following:

''(l)(1) For purposes of this subsection—

''(A) the term 'head of an agency' means—

''(i) the head of an Executive agency, other than the Department of Defense or the Government Accountability Office;

''(ii) the head of the United States Postal Service;

''(iii) the Director of the Administrative Office of the United States Courts, with respect to employees of the judicial branch; and

''(iv) any employing authority described under subsection (k)(2), other than the Government Accountability Office; and

''(B) the term 'limited time appointee' means an annuitant appointed under a temporary appointment limited to 1 year or less.

''(2) The head of an agency may waive the application of subsection (a) or (b) with respect to any annuitant who is employed in such agency as a limited time appointee, if the head of the agency determines that the employment of the annuitant is necessary to—

''(A) fulfill functions critical to the mission of the agency, or any component of that agency;

''(B) assist in the implementation or oversight of the American Recovery and Reinvestment Act of 2009 (Public Law 111–5) or the Troubled Asset Relief Program under title I of the Emergency Economic Stabilization Act of 2008 (12 U.S.C. 5201 et seq.);

''(C) assist in the development, management, or oversight of agency procurement actions;

''(D) assist the Inspector General for that agency in the performance of the mission of that Inspector General;

''(E) promote appropriate training or mentoring programs of employees;

''(F) assist in the recruitment or retention of employees; or

''(G) respond to an emergency involving a direct threat to life of property or other unusual circumstances.

''(3) The head of an agency may not waive the application of subsection (a) or (b) with respect to an annuitant—

''(A) for more than 520 hours of service performed by that annuitant during the period ending 6 months following the individual's annuity commencing date;

''(B) for more than 1040 hours of service performed by that annuitant during any 12-month period; or

''(C) for more than a total of 3120 hours of service performed by that annuitant.

''(4)(A) The total number of annuitants to whom a waiver by the head of an agency under this subsection or section 8468(i) applies may not exceed 2.5 percent of the total number of full-time employees of that agency.

''(B) If the total number of annuitants to whom a waiver by the head of an agency under this subsection or section 8468(i) applies exceeds 1 percent of the total number of full-time employees of that agency, the head of that agency shall submit to the Committee on Homeland Security and Governmental Affairs of the Senate, the Committee on Oversight and Government Reform of the House of Representatives, and the Office of Personnel Management—

''(i) a report with an explanation that justifies the need for the waivers in excess of that percentage; and

''(ii) not later than 180 days after submitting the report under clause (i), a succession plan.

''(5)(A) The Director of the Office of Personnel Management may promulgate regulations providing for the administration of this subsection.

''(B) Any regulations promulgated under subparagraph (A) may—

''(i) provide standards for the maintenance and form of necessary records of employment under this subsection;

''(ii) to the extent not otherwise expressly prohibited by law, require employing agencies to provide records of such employment to the Office of Personnel Management or other employing agencies as necessary to ensure compliance with paragraph (3);

''(iii) authorize other administratively convenient periods substantially equivalent to 12 months, such as 26 pay periods, to be used in determining compliance with paragraph (3)(B);

''(iv) include such other administrative requirements as the Director of the Office of Personnel Management may find appropriate to provide for the effective operation of, or to ensure compliance with, this subsection; and

''(v) encourage the training and mentoring of employees by any limited time appointee employed under this subsection.

''(6)(A) Any hours of training or mentoring of employees by any limited time appointee employed under this subsection shall not be included in the hours of service performed for purposes of paragraph (3), but those hours of training or mentoring may not exceed 520 hours.

''(B) If the primary service performed by any limited time appointee employed under this subsection is training or mentoring of employees, the hours of that service shall be included in the hours of service performed for purposes of paragraph (3).

''(7) The authority of the head of an agency under this subsection to waive the application of subsection (a) or (b) shall terminate 5 years after the date of enactment of the Part-Time Reemployment of Annuitants Act of 2009.''; and

(3) in subsection (m) (as so redesignated)—

(A) in paragraph (1), by striking ''(k)'' and inserting ''(l)''; and

(B) in paragraph (2), by striking ''or (k)'' and inserting ''(k), or (l)''.

(b) FEDERAL EMPLOYEE RETIREMENT SYSTEM.—Section 8468 of title 5, United States Code, is amended—

(1) by redesignating subsection (i) as subsection (j);

(2) by inserting after subsection (h) the following:

''(i)(1) For purposes of this subsection—

''(A) the term 'head of an agency' means—

''(i) the head of an Executive agency, other than the Department of Defense or the Government Accountability Office;

''(ii) the head of the United States Postal Service;

''(iii) the Director of the Administrative Office of the United States Courts, with respect to employees of the judicial branch; and

''(iv) any employing authority described under subsection (h)(2), other than the Government Accountability Office; and

''(B) the term 'limited time appointee' means an annuitant appointed under a temporary appointment limited to 1 year or less.

''(2) The head of an agency may waive the application of subsection (a) with respect to any annuitant who is employed in such agency as a limited time appointee, if the head of the agency determines that the employment of the annuitant is necessary to—

''(A) fulfill functions critical to the mission of the agency, or any component of that agency;

''(B) assist in the implementation or oversight of the American Recovery and Reinvestment Act of 2009 (Public Law 111–5) or the Troubled Asset Relief Program under title I of the Emergency Economic Stabilization Act of 2008 (12 U.S.C. 5201 et seq.);

''(C) assist in the development, management, or oversight of agency procurement actions;

''(D) assist the Inspector General for that agency in the performance of the mission of that Inspector General;

''(E) promote appropriate training or mentoring programs of employees;

''(F) assist in the recruitment or retention of employees; or

''(G) respond to an emergency involving a direct threat to life of property or other unusual circumstances.

''(3) The head of an agency may not waive the application of subsection (a) with respect to an annuitant—

''(A) for more than 520 hours of service performed by that annuitant during the period ending 6 months following the individual's annuity commencing date;

''(B) for more than 1040 hours of service performed by that annuitant during any 12-month period; or

''(C) for more than a total of 3120 hours of service performed by that annuitant.

''(4)(A) The total number of annuitants to whom a waiver by the head of an agency under this subsection or section 8344(l) applies may not exceed 2.5 percent of the total number of full-time employees of that agency.

''(B) If the total number of annuitants to whom a waiver by the head of an agency under this subsection or section 8344(l) applies exceeds 1 percent of the total number of full-time employees of that agency, the head of that agency shall submit to the Committee on Homeland Security and Governmental Affairs of the Senate, the Committee on Oversight and Government Reform of the House of Representatives, and the Office of Personnel Management—

''(i) a report with an explanation that justifies the need for the waivers in excess of that percentage; and

''(ii) not later than 180 days after submitting the report under clause (i), a succession plan.

''(5)(A) The Director of the Office of Personnel Management may promulgate regulations providing for the administration of this subsection.

''(B) Any regulations promulgated under subparagraph (A) may—

''(i) provide standards for the maintenance and form of necessary records of employment under this subsection;

''(ii) to the extent not otherwise expressly prohibited by law, require employing agencies to provide records of such employment to the Office or other employing agencies as necessary to ensure compliance with paragraph (3);

''(iii) authorize other administratively convenient periods substantially equivalent to 12 months, such as 26 pay periods, to be used in determining compliance with paragraph (3)(B);

''(iv) include such other administrative requirements as the Director of the Office of Personnel Management may find appropriate to provide for effective operation of, or to ensure compliance with, this subsection; and

''(v) encourage the training and mentoring of employees by any limited time appointee employed under this subsection.

''(6)(A) Any hours of training or mentoring of employees by any limited time appointee employed under this subsection shall not be included in the hours of service performed for purposes of paragraph (3), but those hours of training or mentoring may not exceed 520 hours.

''(B) If the primary service performed by any limited time appointee employed under this subsection is training or mentoring of employees, the hours of that service shall be included in the hours of service performed for purposes of paragraph (3).

''(7) The authority of the head of an agency under this subsection to waive the application of subsection (a) shall terminate 5 years after the date of enactment of the Part-Time Reemployment of Annuitants Act of 2009.''; and

(3) in subsection (j) (as so redesignated)—

(A) in paragraph (1), by striking ''(h)'' and inserting ''(i)''; and

(B) in paragraph (2), by striking ''or (h)'' and inserting ''(h), or (i)''.

(c) RULE OF CONSTRUCTION.—Nothing in the amendments made by this section may be construed to authorize the waiver of the hiring preferences under chapter 33 of title 5, United States Code in selecting annuitants to employ in an appointive or elective position.

(d) TECHNICAL AND CONFORMING AMENDMENTS.—Section 1005(d)(2) of title 39, United States Code, is amended—

(1) by striking ''(l)(2)'' and inserting ''(m)(2)''; and

(2) by striking ''(i)(2)'' and inserting ''(j)(2)''.

SEC. ___3. GENERAL ACCOUNTABILITY OFFICE REPORT.

(a) IN GENERAL.—Not later than 3 years after the date of enactment of this Act, the Comptroller General of the United States shall submit to the Committee on Homeland Security and Governmental Affairs of the Senate and the Committee on Oversight and Government Reform of the House of Representatives a report regarding the use of the authority under the amendments made by section ___2.

(b) CONTENTS.—The report submitted under subsection (a) shall—

(1) include the number of annuitants for whom a waiver was made under subsection (l) of section 8344 of title 5, United States Code, as amended by this title, or subsection (i) of section 8468 of title 5, United States Code, as amended by this title; and

(2) identify each agency that used the authority described in paragraph (1).

(c) AGENCY DATA.—Each head of an agency (as defined under sections 8344(l)(1) and 8468(i)(1)(A) of title 5, United States Code, as added by section ___2 of this title) shall—

(1) collect and maintain data necessary for purposes of the Comptroller General report submitted under subsection (a); and

(2) submit to the Comptroller General that data as the Comptroller General requires in a timely fashion.

AUTHORITY FOR COMMITTEES TO MEET

COMMITTEE ON BANKING, HOUSING, AND URBAN AFFAIRS

Mr. MERKLEY. Mr. President, I ask unanimous consent that the Committee on Banking, Housing, and Urban Affairs be authorized to meet during the session of the Senate on June 3, 2009 at 2 p.m. to conduct a hearing entitled ''A Fresh Start For New Starts.''

The PRESIDING OFFICER. Without objection, it is so ordered.